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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

VITA FOOD PRODUCTS OF ILLINOIS, INC.,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

PATRICK W. O'BRIEN
WATSON B. TUCKER
DOUGLAS A. POE
231 South LaSalle Street
Suite 1955
Chicago, Illinois 60604
Attorneys for Petitioner

Of Counsel:

MAYER, BROWN & PLATT
231 South LaSalle Street
Suite 1955
Chicago, Illinois 60604
(312) 782-0600

CHAS. P. YOUNG-CHICAGO

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Petitioner, Vita Food Products of Illinois, Inc., ("Vita"), seeks review of the judgment and decision of the United States Court of Appeals for the Seventh Circuit which, reversing the judgment of the United States District Court for the Northern District of Illinois, held, *inter alia*, that residues of DDT and dieldrin in smoked chubs which are processed by Petitioner are "food additives" within the meaning of Section 201(s) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(s). This case presents an important "question in the administration of the Federal Food, Drug and Cosmetic Act" (*62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951)) which should be considered and resolved by this Court.

OPINIONS BELOW

The opinion of the United States District Court for the Northern District of Illinois, reported at 356 F. Supp. 1213, is reproduced in the Appendix (A-11). The opinion of

the United States Court of Appeals for the Seventh Circuit, which has not as yet been reported, is reproduced in the Appendix (A-26).

JURISDICTION

The judgment of the Court of Appeals for the Seventh Circuit was entered on August 28, 1974. The mandate of the Court of Appeals was stayed pending the filing of this Petition for Certiorari. (A-46). This Petition is filed within 90 days of entry of the Court of Appeals' judgment. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

QUESTION PRESENTED

Whether the traces of the chemicals DDT and dieldrin, found in the fish smoked and sold by Petitioner in interstate commerce, are "food additives" within the meaning of the Federal Food, Drug and Cosmetic Act where (a) DDT and dieldrin become incorporated into the fish smoked by Petitioner while the fish are in their natural state prior to the time they are caught; (b) neither DDT nor dieldrin is added to nor becomes a component of, the fish after they are caught or during the smoking or distributing process by Petititoner; and (c) neither DDT nor dieldrin is used by Petitioner or by any other person on, or with respect to, the fish in their natural state, or in the course of the smoking or distributing process, for any purpose or in any manner whatsoever.

STATUTORY PROVISIONS INVOLVED

The pertinent sections of the Federal Food, Drug and Cosmetic Act ("FDCA") are the following:

Section 201(s), 21 U.S.C. § 321(s):

> "The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in

its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"(3) a color additive; or

"(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958 pursuant to this chapter, the Poultry Products Inspection Act or the Meat Inspection Act of March 4, 1907, as amended and extended; or

"(5) a new animal drug."

Section 402(a), 21 U.S.C. § 342(a):

"A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injur-

ious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title:

> *Provided,* that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. . . ."

Sect on 409(a), 21 U.S.C. § 348(a):

> '(a) A food additive shall, with respect to any par icular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(c) of section 342(a) of this title, unless—
>
> "(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or
>
> "(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.
>
> "While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342(a) of this title."

STATEMENT OF THE CASE

Factual Background

Vita operates a plant in Chicago, where it smokes or otherwise processes various species of fish, including chubs, whitefish, salmon, stable, sturgeon, eel, trout, herring and whiting. Although these fish are caught in various places throughout the world, the Government's evidence in the instant case involved only one species of fish from one location: chubs from Lake Michigan.* Chubs represent approximately ⅓ of Vita's production. In 1971, Vita smoked

* The chub is a small fish, weighing about ⅓ pound. It is in the same family as the herring and the whitefish, although it is smaller than the latter. The chub is found only in the waters of Lake Michigan, Lake Superior and Lake Huron.

600,000 pounds of chubs, of which 400,000 came from Lake Michigan and 200,000 from Lake Superior. Vita buys its Lake Michigan chubs directly from the fisherman. Chubs are prepared in only one fashion: they are smoked. They are eaten cold, usually at room temperature.

Two chemical pesticides are involved in the instant case —DDT and dieldrin.* DDT has been used extensively throughout the world. It has been used extensively on crops in the United States and also to control mosquitoes and to minimize tree losses caused by Dutch Elm Disease.

Because of the persistence of DDT in the environment, it is commonly thought that the use of DDT should either be phased out or limited. Prior to January 1, 1973, the use of DDT in the United States had been reduced by approximately 80%. Subsequent to January 1, 1973, pursuant to an order of the Federal Environmental Protection Agency, the use of DDT in the United States has been nearly entirely eliminated.

Nevertheless, DDT and its derivatives are currently universally found in all living tissue. The concentration of DDT in human tissue is approximately 8 to 10 parts per million ("ppm"). Apparently because of the declining use of DDT, recent studies indicate that its concentration in human tissue is declining.

DDT is similarly found in fish, including chubs which are caught in Lake Michigan and which are smoked by Vita and are subsequently sold in interstate commerce. It is undisputed that no one at any time or for any purpose adds DDT to the chubs. Rather, the chubs obtain DDT naturally, through contact with their environment or through prenatal

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* Little, if anything, can be learned about dieldrin from the record in this case. The existence of dieldrin has been known for several years, but no evidence of dieldrin's uses, purposes, advantages or disadvantages was submitted during the trial. Like DDT, dieldrin finds its way into some living tissue, but the Government did not attempt to demonstrate how this process occurred or what effect the existence of dieldrin in the envioronment may have.

transfer from their parents prior to the time that they are caught by fishermen and sold to Vita.

Food and Drug Administration ("FDA") Action Regarding DDT

DDT has been used as a pesticide chemical in connection with the production of various food products, including livestock and harvested farm products. The amount of DDT permitted to remain in such products is regulated by the FDA by means of tolerance levels established under the *pesticide* provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"), (21 U.S.C. § 346a),* as opposed to the *food additive* provisions.

The FDA has not, however, set any tolerance levels for concentration of DDT or dieldrin in fish, presumably because neither of these chemicals is *used* in connection with the raising, harvesting or processing of fish. All of the DDT and dieldrin tolerances presuppose a use of these pesticide chemicals in conjunction with the regulated food in question.

While the FDA has never set tolerance levels for DDT and dieldrin in fish, it did set a 5 ppm "guideline" for DDT in fish by means of a press release issued on April 22, 1969. This "guideline" has been used by the Government in commencing actions under the FDCA and seeking injunctive relief, including the instant case, even though the press release was never promulgated as a regulation or adopted pursuant to a specifically authorized statutory provision.**

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* The tolerance levels for various products are published in 40 C.F.R. § 180.147. Tolerance levels have likewise been established for dieldrin. 40 C.F.R. § 180.137.

** The "guideline" is reproduced in CCH Food Drug Cosmetic Law Rep. [1967-1970 Transfer Binder] ¶60,243. There is no indication from the "guideline" that DDT was considered to be a "food additive," or that it was *used* in connection with smoked or raw fish. Compare 21 C.F.R. § 121.1230, which regulates sodium nitrite used in processing smoked chubs.

Later in 1969, FDA tested random samples of Vita's Lake Michigan chubs and found, or believed that it found, DDT concentrations in excess of 5 ppm. Thereafter a hearing was held, the only purpose of which was to notify Vita that its chubs exceeded the 5 ppm "guideline". Between mid-1969 and mid-1971 a series of meetings were held between FDA and industry representatives, including Vita, to attempt to work out a system for sampling and testing Lake Michigan chubs.

The Commencement of this Litigation

In August, 1970, in the midst of the discussions between FDA and Vita, the Government filed a Complaint for Injunction (A-1), pursuant to Section 302(a) of the FDCA, 21 U.S.C. § 332(a), to require Vita to test all of its fish (not merely Lake Michigan chubs) for DDT and dieldrin and to enjoin Vita from shipping any fish in interstate commerce where the DDT concentration therein exceed 5 ppm and the dieldrin concentration exceed 0.3 ppm.* Following the commencement of the lawsuit, and as a direct result thereof, Vita voluntarily stopped processing Lake Michigan chubs for sale in interstate commerce. Vita, however, planned to resume selling chubs in interstate commerce as soon as it could do so within the FDA "guidelines."

Settlement of the lawsuit ultimately proved to be impossible for two basic reasons. In the first instance, the FDA and Vita used different laboratories to conduct the tests, with the result that different conclusions were reached. It should be noted, however, that the discrepancies in test results presented in evidence to the District Court ranged between approximately 4 ppm and 9 ppm—a quantitative difference of 5 one-millionths. Vita relied primarily upon testing performed by a laboratory operated by the Ameri-

* Although Vita has numerous competitors in the Northern District of Illinois, where the suit was commenced, and although FDA was fully aware of the identity of these competitors, the Government named only Vita as defendant.

can Meat Institute in Chicago, the results of which indicated a DDT concentration of less than 5 ppm. The FDA, on the other hand, produced test results using its own Chicago laboratory, which concluded that the test samples contained a DDT concentration in excess of 5 ppm.

The second reason why settlement became impossible was that the FDA insisted that a consent decree cover *all* of Vita's fish and that the manner of sampling and testing be left open for FDA to specify at a later date.

The Trial and the Decision of the District Court

The trial in the instant case lasted more than two weeks and produced a transcript of almost 1,300 pages, much of which was devoted to highly technical matters concerning various methods for testing the DDT concentrations in fish and the effectiveness of the various testing methods. At the trial, the Government's theory was that DDT and dieldrin in Vita's chubs are "food additives" within the meaning of Section 201(s) of the FDCA, 21 U.S.C. § 321(s). Under the Government's theory, it would not have had to prove that DDT or dieldrin were actually harmful to humans. Rather, it would only have had to establish that DDT and dieldrin were not "generally recognized as safe . . . under the conditions of [their] intended use" among experts qualified to make such a determination, and that the concentrations of DDT and dieldrin in the chubs exceeded 5 ppm and 0.3 ppm, respectively.

At the conclusion of the trial, the District Judge issued a Memorandum Opinion and Order (A-11), in which he concluded (a) that DDT and dieldrin as found in Vita's chubs were not "food additives" within the meaning of the FDCA; (b) that, even if DDT were a "food additive" under the FDCA, the Government had failed to prove by the greater weight of the evidence that Vita's chubs contained DDT or dieldrin concentrations in excess of 5 ppm or 0.3 ppm, respectively; and (c) that the Government had not presented sufficient evidence to warrant a finding that DDT

and dieldrin in Vita's chubs constituted a health hazard. Accordingly, the District Court ordered that judgment be entered in favor of Vita.

The Decision of the Court of Appeals

The Court of Appeals reversed the judgment of the District Court both on the legal question of whether DDT and dieldrin were "food additives" within the meaning of the FDCA and on the factual question of whether the Government had established that the DDT and dieldrin concentrations in Vita's fish exceeded the FDA's "guidelines". With respect to the "food additive" issue, the Court of Appeals held that, "[a]lthough it may seem odd to place the label 'additive' on a chemical substance which was a component of the raw product and which is not changed by processing" (A-37), nevertheless this was the result that Congress had intended.

With respect to the discrepancies in the test results, the Court of Appeals concluded that "[h]owever imprecise [the AOAC*] method may be, the record indicates that it is the best method that can be used." (A-44). The Court of Appeals concluded that "without disagreeing with the district court's observation that the AOAC method falls short of perfect certainty, we cannot accept the view that it may not be used to evaluate [Vita's] compliance with the [FDA] guidelines." (A-44).**

Accordingly, the Court of Appeals reversed the judgment of the District Court and remanded the case for the entry of appropriate relief for the Government. (A-45).

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* The testing method used by both the FDA and Vita was generally referred to during the trial as the "AOAC" method because it was published in the Journal of the Association of Official Analytical Chemists.

** The Court of Appeals also noted that "[n]either party has contested the applicability of the F.D.A.'s 5 ppm enforcement guideline." A-41. In fact, Vita argued in the District Court that the guideline was unreasonable and that the FDA could not enforce it as if it were a regulation or a statute.

REASONS FOR GRANTING THE WRIT

This Case Presents an Important Question Concerning the Administration of the Federal Food, Drug and Cosmetic Act Which Has Not Been, But Should Be, Considered by This Court: Whether the Traces of the Chemicals DDT and Dieldrin Found in the Fish Smoked and Sold by Petitioner in Interstate Commerce are "Food Additives" Within the Meaning of the Act.

1. Introduction.

At the outset, it is important to emphasize what is *not* involved in the instant case. This case does not involve the merits or demerits, the advantages or disadvantages, of the use of DDT in any circumstances. Not only does Vita not "use" DDT in any sense of the word, but it has no interest whatsoever in whether or not the use of DDT or dieldrin as a pesticide chemical is permitted, or restricted, by any governmental authority. The sole issue of statutory construction is whether the DDT found in Vita's chubs constitutes a "food additive" within the meaning of the Federal Food, Drug and Cosmetic Act.

It should also be emphasized that a conclusion that the DDT in question here is *not* a "food additive" does *not* close the door to regulation by the FDA.* As the District Court noted:

> "It should be made crystal clear that these findings do not open the gate to an area of abandonment of con-

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* Various alternatives are available to the Government apart from its "food additive" theory. For example, 21 U.S.C. § 342(a)(1) provides that a food shall be considered to be adulterated:

> "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

cern on the part of processors of food. Neither do they restrain the Food and Drug Administration from pursuing a severe program of monitoring processors of smoked fish in its effort to keep out of interstate commerce food that constitutes a known health hazard." (A-25).*

Finally, it should be emphasized that there is no factual dispute in the instant case concerning the stage at which DDT and dieldrin become incorporated into Vita's chubs. While the source of these chemicals is unknown, the process of incorporation occurs entirely when the fish are in their natural state in Lake Michigan prior to the time that they are caught. Neither DDT nor dieldren is added to, or becomes a component of, the fish after they are caught or during the manufacturing or distributing process. Nor is DDT or dieldrin deliberately used by any person for any purpose on or with respect to the fish in their natural state in the manner that DDT may be used on agricultural crops

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If this statutory provision were invoked, it would of course be incumbent upon the Government to prove that the quantity of DDT and/or dieldrin allegedly found in Vita's fish would render the fish injurious to health.

Similarly, the Government could proceed under 21 U.S.C. § 342(a)(3), which provides that a food will be deemed to be adulterated if it consists:

> "in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."

Again, it would be necessary for the Government to establish that the fish in question were rendered "unfit for food" by reason of the DDT and dieldrin that they contained.

Thus the basic underlying issue is whether the Government should be required to prove that there is any danger to the public health arising from the consumption of Vita's fish, or whether the Government may summarily banish the fish from interstate commerce on theory that DDT and dieldrin are "food additives" that have not been adequately tested as "additives".

* See also *Toilet Goods Ass'n* v. *Finch*, 419 F.2d 21, 27-28 (2nd Cir. 1969).

as a pesticide chemical. The simple fact is that DDT and dieldrin migrate to the fish from a source or sources unknown while they remain in their natural habitat in Lake Michigan before there is any human contact with them either by fishermen or by Vita.

The basic question presented is whether, under the circumstances here presented, DDT and dieldrin constitute "food additives" within the meaning of the FDCA. In so holding, the Court of Appeals has ignored the admonition of this Court that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *United States* v. *An Article of Drug*, 394 U.S. 784, 800 (1969), quoting, *62 Cases of Jam* v. *United States*, 340 U.S. 593, 600 (1951).

2. Legislative history of the Food Additives Amendment.

The situation presented in the instant case is very far removed from that to which Congress was responding when it enacted the Food Additives Amendment of 1958, 72 Stat. 1784, 21 U.S.C. § 321(s).* Congress was concerned because a large number of substances were being deliberately added to foods as preservatives, nutritional supplements, color modifiers, flavoring agents, and the like,** without any recog-

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* The Food Additives Amendment, Pub. Law 85-929, 72 Stat. 1784, is entitled "An Act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety."

** In the course of the hearings on the Food Additives Amendment, the Commissioner of the Food and Drug Administration, George P. Larrick, listed more than 45 examples of uses for which additives were employed. *Hearings before the Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce of the House of Representatives on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food*, 85th Congress, p. 467 (1957-1958) [hereinafter cited as *Food Additives Hearings*].

nized procedures for pre-testing the safety of these ingredients prior to their introduction on the market. Extensive hearings were held during each congressional session between 1950 and 1958, culminating in eleven days of hearings during the 85th Congress before the Subcommittee on Health and Science of the House Interstate and Foreign Commerce Committee. Numerous witnesses expressed concern that chemicals of various types were being added to food without any governmentally-supervised testing program to determine that the additives were safe in the quantities used. Typical of this testimony was that of Elliot L. Richardson, who was then the Assistant Secretary of the Department of Health, Education, and Welfare ("HEW"):

> "The original Food and Drug Act of 1906 did not, nor does the present Food, Drug, and Cosmetic Act of 1938, require a manufacturer to establish the safety of a chemical before he adds it to food. Firms that are careless or irresponsible can add new substances to the food supply without any testing at all.
>
> "If they add materials of unknown or uncertain toxicity, we have no way to prevent it; and, if any of these substances are actually harmful, they cannot be eliminated from the food supply until someone, ordinarily the Government itself, develops the scientific evidence adequate to support legal action. Obtaining such evidence may require years. Meanwhile, the public health may be endangered." *Food Additives Hearings* 421.*

Other government agencies, including the Department of Commerce, likewise urged Congress to enact legislation providing for the testing of new additives to determine their safety before the food in which they were used was introduced into commerce. See, *e.g.*, Letter from Commerce

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* See, in addition, the statement of FDA Commissioner George P. Larrick, *Food Additives Hearings* 447.

Secretary Sinclair Weeks to Oren Harris, Chairman of the House Committee on Interstate and Foreign Commerce, *Food Additives Hearings* 25; Statement of Rep. Leonor K. Sullivan, *Food Additives Hearings* 166.

The fact that chemicals could be *deliberately added to food* without any requirement of an adequate testing program was, therefore, one of the two principal flaws in existing law which Congress attempted to cure when it passed the Food Additives Amendment of 1958. As stated by the Senate Committee on Labor and Public Welfare:

> "[E]xisting law permits any processor who chooses to pay no heed either to the public's health or to his continuance in one particular line of business to unfairly compete with responsible processors, to defy the Food and Drug Administration and to endanger the health of millions by using an untested additive for as long a time as it may take for the Government to suspect the deleteriousness of his additives, schedule research into its properties and effects, and, finally—perhaps years later—to begin the years-long experiments needed to prove the particular additive safe or unsafe. The huge loophold is 1 of 2 flaws in existing law which, through this measure, we are attempting to fill. This bill, if enacted, will require the processor who wants to add a new and unproven additive to accept the responsibility now voluntarily borne by all responsible food processors of first proving it to be safe for ingestion by human beings." S. Rep. No. 2422, 85th Cong., 2d Sess., 3 U.S. Code Cong. & Admin. News 5301 (1958).

Congress also had a second basic purpose when it enacted the Food Additives Amendment, namely, to *liberalize* the law to permit the use of food additives which had been adequately tested. Under the law as it existed in 1958, and specifically under 21 U.S.C. §§ 342(a)(2)(A) and 346, all poisonous or deleterious substances which were added to food were proscribed except those that were required in the production of the food or that could not be avoided by good

manufacturing practices. The state of the law tended to retard advances in food technology because substances were prohibited which may have had a salutary effect in the production of food. See, *e.g.*, 104 Cong. Rec. 17413 (1958) (remarks of Congressman Harris). This was one of the factors which moved the HEW to request changes in existing law to permit the use of food additives in safe quantities.*

This apparent restrictiveness of existing law in relation to the use of additives in food was the second criticism of the *status quo* to which Congress responded in adopting the Food Additives Amendment. As explained in the Senate report accompanying the Amendment:

> "The second flaw in existing law which has proved detrimental to consumers, the processors, and to our national economy and which this bill seeks to remove is a provision which has inadvertently served to unnecessarily proscribe the use of additives that could enable the housewife to safely keep food longer, the processor to make it more tasteful and appetizing, and the Nation to make use of advances in technology calculated to increase and improve our food supplies. Your committee agrees with the Food and Drug Administration that existing law should be changed to permit the use of such additives as our technological scientists may produce and which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted by the Food and Drug Administration as safe." **

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* See, *e.g.*, Letter from HEW Secretary M. B. Folson to Speaker of the House Sam Rayburn, ***Food Additives Hearings*** 28-29. In addition, see, *e.g.*, ***Food Additives Hearings*** 68-69, (testimony of Charles Wesley Dunn, General Counsel, Grocery Manufacturers of America).

** S. Rep. No. 2422, 85th Cong., 2d Sess., 3 U.S. Code Cong. & Admin. News 5301 (1958). To the same effect is the discussion in H. Rep. No. 2284, 85th Cong., 2d Sess. 1-2 (1958).

Congress therefore enacted, as part of the Food Additives Amendment, an elaborate procedure to permit the *use* of proposed additives but only after tests for safety conducted before the food in which they are actually *used* is introduced into commerce. These provisions, contained in 21 U.S.C. § 348, parallel procedures enacted in 1954 for the regulation of pesticide chemicals used in or on agricultural products (21 U.S.C. § 346a). Briefly, Section 348 provides that any person who intends to use a food additive may file a petition with the Secretary of HEW asking for the issuance of a regulation detailing "the conditions under which such additive may be safely used" (§ 348(b)(1)). The petition must contain, *inter alia*, a statement of the conditions under which the additive will be used, including all directions, recommendations, and suggestions for the use of the additive (§ 348(b)(2)(B)); all data relating to the physical or other technical effect which the additive is intended to produce, together with the quantity of the additive that is required to produce the desired effect (§ 348(b)(2)(C)); and full reports of investigations conducted to determine the safety of the additive for use under the indicated circumstances (§ 348(b)(2)(E)). The data submitted is then examined by FDA scientists, who make an independent determination concerning the safety of the new ingredient for use in food.* If the evidence demonstrates that the proposed additive would be a suitable component of food, HEW then issues a regulation stating the safe permissible uses for the substance and placing any restrictions deemed necessary on the quantity or manner of addition of the additive and the labeling and packaging of the food (§ 348(c)). Such elaborate procedures for obtaining the approval of a "food additive" obviously make no sense if applied to substances that unintentionally or accidentally get into food, as opposed to those that are deliberately intended to be used in, or in connection with, the production

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* See generally Larrick, *The New Food-Additives Law*, 13 Food, Drug, Cosm. L.J. 634 (1958).

of food. Cf. *Toilet Goods Ass'n* v. *Finch*, 419 F.2d 21, 26-27 (2nd Cir. 1969).

Thus, the structure of the Food Additives Amendment indicates that Congress intended to deal only with certain substances which were deliberately used on or in connection with food. Indeed Section 348 provides that a food additive shall, *with respect to any particular use or intended use of such additives*, be considered to be unsafe unless the additive and *its use or intended use* are in conformity with either an exemption or a regulation issued under Section 348. Section 348 is not concerned with components of food generally or in the abstract but only those which are used or intended for use in a particular manner.

Finally, Congress specifically focused upon the concept of "food additive" and its understanding confirms an intention to distinguish between substances deliberately used in connection with food and those which unintentionally or accidentally became part of the food. The particular formula which Congress eventually chose is contained in 21 U.S.C. § 321(s):

> "The term 'food additive' means any substance *the intended use* of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance *intended for use* in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food . . . ." (Emphasis added.)

The definition of "food additive" in Section 321(s) specifically *excludes, inter alia,* pesticide chemicals in or on raw agricultural commodities or those used in the production, storage, or transportation of any raw agricultural commodity.

The Committee reports accompanying the Food Additives Amendment deal with some specificity with the differ-

ent categories of food additives, distinguishing those which were intended to fall within, and those without, the scope of the Amendment. Both the House and Senate reports, following a tripartite system of categorization which had been consistently adhered to during the hearings, defined food additives as "intentional", "incidental", and "accidental." The pertinent discussion of the concepts, as elaborated in the Senate report, is as follows:

> "The [Food Additives Amendment] covers substances which are added intentionally to food. These additives are generally referred to as 'intentional additives.'
>
> "The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as 'incidental additives.'
>
> "*The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.*
>
> "On the other hand, *substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation.* These additives are generally referred to as 'accidental additives,' since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. *If accidental additives do get into food, the provisions of the Food, Drug and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.*"* (Emphasis added.)

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* S. Rep. No. 2422, 85th Cong., 2d Sess., 3 U.S. Code Cong. & Admin. News 5300, 5303-5304 (1958). An identical discussion is also contained in H. Rep. No. 2284, 85th Cong., 2d Sess. 3-4 (1958).

The essential distinction which Congress intended, therefore, was to differentiate between those substances which are deliberately used in connection with food production ("intentional" and "incidental" additives), which would be subject to the pre-testing provisions of the Amendment, and those substances which became components of food in any other manner, whether by accident or otherwise unintentionally.*

This understanding, found in the committee reports, also emerges from the congressional proceedings prior to the enactment of the Food Additives Amendment. Among the bills introduced dealing with the question of food additives was H.R. 8112, 85th Cong., 1st Sess., introduced by Representative Miller, which specifically distinguished between intentional and incidental additives, defining the latter as follows:

> "The term 'incidental food additive' means any substance *intended for use* in manufacturing, packing, processing, preparing, treating, packaging, or transporting food which forseeably results, *in the course of good manufacturing practice*, in its getting into the food; including any radioactive material intended for such use or as a source for the irradiation of food." *Food Additives Hearings* 13. (Emphasis added.)

The Department of HEW took the position that the substances so defined as "incidental" additives should be covered by the legislation, but the Department did object to the establishment of separate procedures dealing with in-

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* See, in addition, testimony of Dr. Robert Blackwell Smith, Jr., President, Medical College of Virginia, *Food Additives Hearings* 89-90; Statement of H. T. Austern, National Canners Ass'n, *Food Additives Hearings* 226.

tentional and incidental additives.* Congress therefore adopted in 21 U.S.C. § 321(s) a single definition of "food additive" which encompasses both substances "intentionally" added and those "incidentally" added to food.

It is abundantly clear from the foregoing consideration of both the legislative history and the structure of the Food Additives Amendment that Congress by enacting that statute was responding to a specific problem, namely, the deliberate use of substances in connection with the preparation of foods. There was obviously no intention to sweep within the purview of Sections 342(a)(2)(C) and 348 all components of food—thereby rendering them adulterated without any demonstration of harmful effects—no matter how, or the circumstances under which, they became incorporated into the food.

It is incontrovertible that the DDT and dieldrin in the present case cannot constitute an "intentional" additive because there is no allegation, nor could there reasonably be any, that defendants or anyone else deliberately adds these substances directly to any fish. Nor may the DDT and dieldrin reasonably be said to be "incidental" additives because this concept was understood by Congress to encompass only those substances deliberately used in the

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* As HEW Secretary Folsom noted in a letter to Representative Harris:

> "It is not clear why there should be the distinction between [intentional and incidental] additives. Whether an additive becomes a component part of the food for the purpose of imparting a desired quality to it or whether it forseeably becomes such a component *as an incident to its use for some other purpose*, it should still go through safety-clearance procedures that are adequate to show that the residues remaining do not constitute a hazard to the public health. We believe that it is undesirable to establish the 2 different groups of additives and to establish . . . 2 distinctly different procedures for permitting their use in food." *Food Additives Hearings* 41. (Emphasis added.)

course of the manufacturing or distribution process. Thus, if the DDT and dieldrin may be considered "additives" in any sense, they are "accidental" additives because they were not used for any purpose by anyone during any stage of the manufacturing process.* However, even if they are considered to be "accidental" additives, the DDT and dieldrin in question are not "food additives" within the meaning of the FDCA and thus the Government, as previously indicated (pages 11-12, *supra*), would have to proceed under other provisions of the Act.

3. Other judicial authorities.

Most of the lower court cases that have considered the same or similar issues under the FDCA have reached a result inconsistent with the Court of Appeals in the instant case and have indicated that an "additive" or an added substance is one which is incorporated into food during the manufacturing process, as opposed to a substance which inheres in potential food, whether animal or plant, in its natural state. For example, in *United States* v. *1232 Cases of American Beauty Brand Oysters*, 43 F.Supp. 749 (W.D. Mo. 1942), the question arose whether shell fragments contained in processed oysters were an "added substance" within the meaning of 21 U.S.C. § 342(a)(1). The District Court held that where an allegedly deleterious substance inheres in the product in its natural state the material could not be considered to be an "added substance" within the contemplation of the statute.

In a somewhat different context the District Court in *Toilet Goods Ass'n* v. *Gardner*, 278 F.Supp. 786 (S.D.N.Y. 1968), *aff'd in part, rev'd in part on other grounds*, 419

* Even this application of the term "accidental additive" does violence to the congressional understanding of the additive concept, however, for there is no indication whatever that Congress intended the term "additive" to extend in any event to components of potential food in its natural state before the commencement of the manufacturing process.

F.2d 21 (2nd Cir. 1969), considered whether the term "additive" as used in the Color Additives Amendment, 74 Stat. 397 (1969) (codified in scattered sections of 21 U.S.C.), could be extended to apply to finished cosmetic products as insisted by the Food and Drug Administration. The Court rejected the FDA's contention in the following terms:

> "I am constrained to reject [the FDA's] argument upon the ground that 'additive' obviously means something to be added. Webster's Third Edition, for example defines additive as 'a substance added to another in relatively small amount to impart or improve desirable properties * * * [such as] a substance added to a foodstuff to improve color * * *' Webster, Third New International Dictionary 24 (1961)." 278 F. Supp. at 790.

The *American Beauty Brand Oysters* and *Toilet Association* cases thus define "additive" in terms of a substance specifically used in connection with the manufacturing process which then becomes a component of a product. The analyses of both cases are obviously inconsistent with the view that an "additive" may consist of a component of a fish existing in its natural state. Thus, whether the DDT and dieldrin are considered to be "accidental" additives or whether they are not "additives" in any sense, it is clear that they are not, in the circumstances of this case, subject to the provisions of the Food Additives Amendment.

Other cases, unlike the Court of Appeals in the present case, have correctly perceived the statutory distinction between pesticide chemicals and food additives. In *United States* v. *Bodine Produce Co.*, 206 F.Supp. 201, 210 (D. Ariz. 1962), the Court pointed out that the DDT found in lettuce was not a "food additive":

> "[B]y the Food Additive Amendment in 1958 . . . Congress tackled the problems of food additives in processed foods in depth. It drew a sharp line between the Food Additives Amendment and the Pesticide

> Chemicals Amendment. ***Thus in the definition of 'food additive' it excluded pesticide chemicals in or on raw agricultural commodities.***" (Emphasis added.)

In *Environmental Defense Fund* v. *United States*, 428 F.2d 1083 (D.C. Cir. 1970), where one of the issues presented was whether DDT was a "food additive", the Court of Appeals noted that "the statute explicitly excluded pesticide chemicals from the definition of the terms 'food additive' and 'color additive'" *Id.* at 1091. See also *Environmental Defense Fund* v. *Ruckelshaus*, 439 F.2d 584, 596 n. 41 (D.C. Cir. 1971); *Fouke & Reynolds* v. *Great Lakes Terminal Warehouse Co.*, 33 Ohio App. 2d 273, 294 N.E. 2d 245, 247 (1972).

It is true that two District Courts have held that DDT found in fish is a "food additive" within the meaning of the FDCA. *United States* v. *Ewig Bros. Co.*, No. 71-C-157 (E.D. Wis. 1972), was a companion case to the present case and was decided by the Court of Appeals in the same opinion. (A-28). *United States* v. *City Smoked Fish Co.*, Civ. No. 33989 (E.D. Mich. 1970), reached the same result. Both cases merely assert that DDT in fish is a "food additive" without explaining why this is so or considering the legislative history of cases discussed herein. While neither case presents a persuasive argument for the result reached, they nevertheless suggest that the question presented herein is a recurring one and that different courts have reached divergent results. This underscores the need for review by this Court of the issue concerning the proper construction of the FDCA raised in the instant case.

4. The decision of the Court of Appeals

In the face of the legislative history of the Food Additives Amendment, the Court of Appeals in the instant case was required to strain mightily in order to reach what it conceived to be the correct result from a policy standpoint. In so doing, the Court of Appeals was required to blur the

legislative history of the FDCA and obscure the plain meaning of the statutory language in order to reach the desired result. Even so, the Court of Appeals conceded that "it may seem odd to place the label 'additive' on a chemical substance which was a component of the raw product and which is not changed by processing . . . ." (A-37). The use of the term "additive" is indeed "odd" in the context of the present case, but the interpretive difficulty is not hard to explain: the Court of Appeals simply misconstrued the Congressional intent in enacting provisions for the testing of "food additives", that is, substances intended to be used on, or in connection with the processing of, food.

The Court of Appeals' analysis begins sensibly enough with the following observations:

> "With respect to the foods for which DDT tolerances have been set, it is reasonable to infer that the rule-making process may have been invoked either by the FDA itself, by manufacturers or distributors of the pesticide, or *by farmers or producers who are interested in using DDT as a pesticide.* Fishermen, however, have never had any interest in using or selling DDT themselves; its presence in the environment is a condition of their work—*and also of the business of distributing or processing fish—for which they are not responsible and which they have no interest whatsoever in perpetuating.* In short, unlike farmers and pesticide salesmen, they have never had any interest in adding DDT to the environment or to the food supply. From their point of view, *it is not an item which is added to their products; it is a natural component of the fish before it is caught, let alone processed.*" A-30. (Emphasis added.)

Similarly, the Court of Appeals noted that:

> "[n]either the purpose to establish a procedure for premarketing clearance of untested food additives, nor

> the intent to permit the evaluation of such products to encompass a consideration of their benefits, as well as their potential for harm.[*] seems directly relevant to the question before us. Rather, we are concerned with products which, at least primarily, *were intended to be regulated as pesticide chemicals rather than as food additives.*" A-32. (Emphasis added.)

While it might have been thought that the foregoing conclusion of the Court of Appeals would have ended the matter—for, as previously noted (page 18, *supra*), the statutory definition of "food additive" expressly excludes "pesticide chemicals"—the Court of Appeals embarked upon an extensive analysis of the regulation of pesticide chemicals. (A-32—A-35.) The Court of Appeals used this analysis as a predicate for its conclusion that

> "congressional efforts to define and regulate adulterated food in the 20 years before 1958 reflected a consistent desire to rationalize the law by reducing the circumstances in which the F.D.A. must prove actual danger to a quantity of food and by establishing a system of tolerances which will both protect the public and enable industry to operate effectively." A-35—A-36.

This statement is accurate insofar as the phrase "reducing the circumstances in which the F.D.A. must prove actual danger" is emphasized. When analyzing the Food Additives Amendment, however, the Court of Appeals, in effect, held that Congress had intended to *eliminate* the circumstances in which the FDA must prove actual danger. Clearly, this is not what Congress intended.

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* This passage of the Court's opinion states, in summary form, the actual Congressional intention which motivated the adoption of the Food Additives Amendment, the intention that had previously been recognized by the same Court of Appeals in *Continental Chemiste Corp.* v. *Ruckelshaus*, 461 F.2d 331, 340-341 (7th Cir. 1972).

The fundamental error of the Court of Appeals occurs in its analysis of the legislative history of the Food Additives Amendment. The Court of Appeals notes that

> "[a]lthough Congress was primarily concerned with substances used by a food processor, neither the language nor the history of the 1958 Act limits its application to such substances. [Footnote omitted.] The words 'the intended use of which' [in the definition of 'food additive'] are not confined, as they easily could have been confined, to use in food processing." A-36.

Here the Court has constructed a strawman argument. To be sure, Congress did not intend the Food Additives Amendment to apply solely to "food processing" (unless that phrase is intended to refer, for example in the case of fish, to the entire process of producing fish from the time that they are caught until they are ultimately purchased by consumers). So long as there is an "intended use" of a substance in connection with food, that substance may well fall within the statutory definition of "food additive." However, in quoting the statutory definition of "food additives" referring to the "intended use" of substances, the Court undermines its contention that a "food additive" may consist of a substance, such as DDT and dieldrin in the instant case, that not only is not "used" with respect to any food, but also clearly is not "intended" to be used in this manner.

The substance of the Court of Appeals' holding is contained in the following passage:

> "Vita has argued that a process, such as smoking, during which nothing new is added to a food, cannot 'transmogrify' a preexisting component of a food into an additive. But whether the food be fish, fruit, or meat, if the component is a pesticide chemical, we think that is exactly what Congress intended.
>
> "*Although it may seem odd to place the label 'additive' on a chemical substance which was a component of the*

> *raw product and which was not changed by processing.* Congress' choice of that label does not result in any 'transmogrification.' *Before processing, DDT is a 'pesticide chemical' on a raw product; after processing, it is an 'additive'.* Since there is no tolerance for DDT on fish, both before and after processing the presence of the DDT causes fish to be adulterated without any proof that it is actually unfit for food. [Vita's] contention, if accepted, would result in the anomaly that a chemical such as DDT would adulterate all raw fish, but adulteration of processed fish would be determined on an uncertain case-by-case basis. We conclude that such a construction of the statute is illogical and unacceptable." A-37. (Emphasis added and footnote omitted.)

The Court of Appeals is unable to cite persuasive legislative history for its extraordinary conclusion that derivatives of DDT and dieldrin contained in fish in their natural state are somehow mysteriously transformed into a "food additive" when that chemical is not at any point in time added to, or used in connection with, the fish after they are caught. The reason for the Court's difficulty in this regard is that Congress, in enacting the Food Additives Amendment had two purposes: (1) to establish a premarketing clearance procedure for substances intended to be *added* to food; and (2) to *liberalize* the then-existing law to permit the addition of substances to food under appropriate safeguards. See generally pages 13-22, *supra*. When the statutory scheme is employed for purposes that were not within the contemplation of Congress, it is hardly surprising that the result reached is not only difficult to square with the legislative history of the Food Additives Amendment, but also that the plain language of the statute must be given a wholly unnatural reading—an "odd" reading, in the words of the Court of Appeals—in order to reach the desired result.

Two related arguments of the Court of Appeals merit comment. The Court held that, after the Food Additives Amendment was enacted, "it became necessary either (a) to make the 'food additive' and the 'pesticide chemical' categories mutually exclusive, or else (b) to enact a specific provision to cover the area of overlap. Congress made the latter choice." A-37—A-38. This conclusion is inconsistent with the statutory definitions of "pesticide chemical" and "food additive." The term "pesticide chemical" is defined as "any substance which, alone, in chemical combination or in formulation with one or more other substances, is 'a pesticide chemical' . . . and *which is used in the production, storage, or transportation of raw agricultural commodities.*" 21 U.S.C. § 321(q). (Emphasis added.) From the definition of "food additive" there is expressly *excluded* "(1) a pesticide chemical in or on a raw agricultural commodity; or (2) a pesticide chemical to the extent that it is intended for use or is *used in the production, storage, or transportation of any raw agricultural commodity: . . .*" 21 U.S.C. § 321(s). Thus, on their face, the respective definitions of "pesticide chemical" and "food additive" are mutually exclusive.

The Court of Appeals attempts to bolster its "overlap" theory (A-37—A-39) by reference to 21 U.S.C. § 342(a)(2)(C), which provides that a food shall be deemed to be adulterated

> "if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided,* that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of section 346 and 348 of this title, not be

> deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, . . ."

A basic defect resulting from reliance upon this provision is that it assumes that the DDT in Vita's fish is, initially, a "pesticide chemical" within the meaning of the FDCA. Since a "pesticide chemical" is defined as "any substance which . . . is used in the production, storage, or transportation of raw agricultural commodities" (21 U.S.C. § 321(q)), and because it is undisputed that the DDT in question here is a natural component of the fish before they are caught, and is *not* "used in the production, storage, or transportation" of the fish, the DDT at issue here is not a "pesticide chemical" within the meaning of the Act, much less a "food additive." Apart from the question of whether fish in Lake Michigan may properly be considered to be "raw agricultural commodities"—that is, "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing" (21 U.S.C. § 321(r))—it is clear that DDT has not been "used in or on a raw agricultural commodity." Thus, the most that the Court of Appeals' analysis establishes is that in some circumstances the *residue* of a pesticide chemical *may* be deemed to be a "food additive" if it has been *used* in or on a raw agricultural commodity. But that is not this case.

The fact that the concepts of "pesticide chemical" and "food additive" are complementary, but that neither applies to this case, is indicated by the legislative history of both provisions. "Pesticide chemicals" that are *used* in or on raw agricultural commodities are regulated under distinct statutory provisions (21 U.S.C. §§ 321(q), 346a) which indicate Congressional recognition of "the peculiar economic,

agricultural, and public health problems which are important in the regulation of pesticide chemicals. Unlike many other chemicals, pesticide chemicals are necessary instruments of agriculture in producing and expanding our food supply. . . ." S. Rep. No. 1635, 83rd Cong., 2d Sess., 2 U.S. Code Cong. & Admin. News 2626, 2629 (1954). However, Congress narrowly delineated the circumstances under which "pesticide chemicals" within the meaning of the FDCA would be regulated. The Senate Report concerning the pesticide chemicals amendments of 1954, 68 Stat. 511, stated:

> "It is intended by these definitions to draw a sharp line of distinction between the subjects covered by this bill and the subjects which are unaffected by it. This bill covers the regulations of the residue from pesticide chemicals which may remain in or on food in its raw or natural state as usually purchased by the consumer or the food processor. Such food would include fresh fruits and vegetables, grains, nuts, eggs, and milk and similar agricultural produce grown or produced at the farm level. It would also include those foods which have been subjected to certain customary postharvest treatment prior to marketing, such as the washing or coloring of fruits in their unpeeled natural form, the stripping of the outer leaves of lettuce, and the preparation of fresh green salads. *This bill does not attempt to regulate the residue from pesticide chemicals which may remain in or on processed, fabricated, or manufactured food other than by limiting the permissible residues on raw agricultural commodities.*" *Id.* at 2631. (Emphasis added.)

The absence of regulation of residues remaining in processed food under the "chemical pesticides" provisions was altered by the Food Additives Amendment, but in so doing Congress did not change the basic criterion that a regulated substance was one intended to be *used* in or on a raw agri-

cultural commodity. Thus the Senate Report on the Food Additives Amendment states:

> "In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal." S. Rep. No. 2422, 85th Cong., 2d Sess., 3 U.S. Code Cong. & Admin. News 5300, 5305 (1958).

Thus the Court of Appeals' notion that DDT is a "pesticide chemical" on a raw product before processing and a "food additive" after processing is correct only to the extent that DDT is *used* in the course of growing, manufacturing or processing a commodity that subsequently becomes a food product. There is no indication whatever that Congress intended the concepts of "pesticide chemical" and "food additive" within the meaning of the FDCA to apply to a component of anything, including fish swimming in Lake Michigan, existing in its natural state.

Finally, the Court of Appeals' characterization of Vita's interpretation of the Food Additives Amendment as "anomalous" and "illogical" cannot provide a substitute for the correct interpretation of the statutory scheme that Congress has enacted. Even if such an anomaly existed, this would not justify the action of the Court of Appeals in rewriting the statutory scheme to conform to what it perceives to be "logical" or "acceptable" as a matter of policy. In short, "[i]f there exists a deficiency in the Act, the cure must come from Congress, not by judicial enlargement of the statute. 'To supply omissions transcends the judicial function. *Iselin* v. *United States*, 270 U.S. 245, 251 (1926)

(Brandeis, J.).'" *Heater* v. *Federal Trade Commission*, — F.2d — (9th Cir., Sept. 11, 1974).* In the instant case, the Court of Appeals, in its enthusiasm "to effectuate the congressional purpose of protecting the public," simply failed to "take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *United States* v. *An Article of Drug*, 394 U.S. 784, 800 (1969), quoting, *62 Cases of Jam* v. *United States*, 340 U.S. 593, 600 (1951).

The instant case has serious, indeed potentially devastating, implications, not only for the fishing industry, but for other industries as well. The Court of Appeals' virtually unlimited interpretation of the "food additive" concept, together with the FDA's imposition of "guidelines" for maximum concentrations of substances in foods by means of press releases, means that the FDA could totally banish any product merely because that product contains a "food additive" that does not conform to the FDA's guidelines. This can be accomplished without any showing whatsoever on the part of the Government that the food in question is in any manner unsafe or otherwise presents any danger to the health of consumers. What is actually anomalous in the present case is that the sweeping powers now assigned by the Court of Appeals to the FDA are premised upon the "food additive" concept which was actually intended by Congress, in part, to *liberalize* prior law so that substances

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* As Judge Friendly wrote for the Court of Appeals in *Toilet Goods Ass'n* v. *Finch*, 419 F.2d 21, 29 (2nd Cir. 1969):

> "[A] court must take the statute as it is, and Congress wrote with great specificity. . . . [T]he language is too clear for us to read it as meaning something different from what it so plainly says, at least in the absence of persuasive legislative history. The case fits perfectly Mr. Justice Brandeis' famous stricture, 'What the Government asks is not a construction of the statute, but, in effect, an enlargement of it by the court, so that what was omitted, presumably by inadvertence, may be included within its scope.' *Iselin* v. *United States*, [*supra*] . . . ."

could be more readily added to foods where no injury to health was present. The Court of Appeals has not only misconstrued the legislative intent in enacting the Food Additives Amendment; it has actually stood that Congressional intention on its head.

CONCLUSION

For the foregoing reasons, Petitioner requests that this Court issue a writ of certiorari to review the judgment and decision of the Court of Appeals for the Seventh Circuit.

Respectfully submitted,

PATRICK W. O'BRIEN
WATSON B. TUCKER
DOUGLAS A. POE
231 South LaSalle Street
Suite 1955
Chicago, Illinois 60604

Attorneys for Petitioner

Of Counsel:

MAYER, BROWN & PLATT
231 South LaSalle Street
Suite 1955
Chicago, Illinois 60604
(312) 782-0600

APPENDIX

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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, Plaintiff v. VITA FOOD PRODUCTS OF ILLINOIS, INC., a corporation, and LAWRENCE T. SCHWEIG, an individual, Defendants.	Judge Napoli Civil Action No. 70C 2246 Complaint for Injunction

The United States of America, Plaintiff herein, by and through WILLIAM J. BAUER, United States Attorney for the Northern District of Illinois, respectfully represents unto this Honorable Court as follows:

1. The proceeding is brought under Section 302(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 332(a)], hereinafter referred to as "the Act", which section specifically invests the several United States District Courts with jurisdiction to enjoin and restrain violations of Section 301 of the Act [21 U.S.C. 331].

2. The defendant, Vita Food Products of Illinois, Inc., is a corporation organized and existing under the laws of the State of Illinois, and trading and doing business at 2222 West Lake Street, Chicago, Illinois, within the jurisdiction of this Court.

3. The defendant, Lawrence T. Schweig, an individual, is vice-president of said corporation and performs his duties as such at Chicago, Illinois, within the jurisdiction of this Court.

4. The defendants have been and are now engaged in receiving after shipment in interstate commerce, articles of food consisting of fish known as chubs and containing the chemical substances, DDT, derivatives of DDT, and dieldrin, in preparing said chubs as smoked chubs, and in pack-

ing and distributing said smoked chubs for human consumption.

5. Said smoked chubs when distributed as aforesaid are adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) in that they contain food additives, namely, DDT, derivatives of DDT, and dieldrin, which are unsafe within the meaning of 21 U.S.C. 348(a) in that said additives and their use and intended use are not in conformity with a regulation or exemption issued pursuant to 21 U.S.C. 348(a) since the total amount of DDT and its derivatives present in said smoked chubs is at a level in excess of the interim limit of 5 parts per million which was established by the Food and Drug Administration for all fish pursuant to an announcement to the public on April 22, 1969 and which is still in effect, and since the presence of dieldrin in smoked fish is not permitted by any regulation or exemption issued pursuant to 21 U.S.C. 348(a).

6. Said defendants violate 21 U.S.C. 331(a) in that they introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce smoked chubs which are adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) as aforesaid.

7. Said defendants violate 21 U.S.C. 331(k) in that they cause chubs, while held for sale after shipment in interstate commerce and containing DDT, derivatives of DDT, and dieldrin as aforesaid, to be prepared, packed and distributed as smoked chubs, which acts result in said smoked chubs being adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) as aforesaid.

8. Said defendants are well aware that their activities are in violation of the Act. The defendants were warned by a hearing held pursuant to 21 U.S.C. 335 on September 16, 1969, in regard to the interstate shipment of smoked chubs which were found to contain DDT, and derivatives thereof in excess of the permitted amount of 5 parts per million. The defendants have also been warned of subsequent inter-

state shipments of smoked chubs which contained dieldrin and excessive amounts of DDT and its derivatives, and of the receipt of fresh chubs which contained dieldrin and excessive amounts of DDT and its derivatives. Despite such warnings the defendants continue to distribute smoked chubs which are adulterated as hereinbefore alleged.

9. Plaintiff is informed and believes that unless restrained by this Honorable Court said defendants will continue to cause said smoked chubs to be adulterated as aforesaid while held for sale after shipment in interstate commerce and to introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce said smoked chubs adulterated as aforesaid.

WHEREFORE, PLAINTIFF PRAYS:

That the defendants, Vita Food Products of Illinois, Inc., and Lawrence T. Schweig, and their officers, agents, servants, employees, representatives, and all persons in active concert or participation with them or any of them be perpetually restrained and enjoined under the provisions of 21 U.S.C. 332(a) from directly or indirectly doing any of the following acts:

A. Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce smoked chubs and other smoked fish, and preparing, packing, and distributing chubs and other fish as smoked chubs and as smoked fish while held for sale after shipment in interstate commerce, unless and until:

(1) appropriate procedures are established and in operation by the defendants to collect representative samples from each shipment of chubs and other fish which are now in possession of the defendants and which are subsequently received by the defendants; to analyze or have analyzed such samples for the presence of DDT, derivatives of DDT, and dieldrin; and if any of the samples are found to contain DDT including

derivatives thereof, in an amount which exceeds the level of 5 parts per million, or are found to contain dieldrin, to dispose of said shipments of chubs and other fish from which those samples were collected in a manner to insure that they are not used for, nor do they become, food for man or animal, unless the pesticide residues are first eliminated;

(2) a system is established and in operation for coding each of the shipments of chubs and other fish received by said defendants in order that proper identification can be made of such shipments with the samples that are collected from such shipments;

(3) duly authorized Food and Drug Inspectors are granted free access to the defendants' plant at 2222 West Lake Street, Chicago, Illinois, for the purpose of making an inspection of such plant, including records, equipment, and fish in the plant, and such inspection shows that the aforesaid procedures and system for sampling, analysis and coding shipments of chubs and other fish received by the defendants have been established and appear to be in proper operation, the costs of any such inspection to be borne by the defendants at the rate of $8.00 per hour and fraction thereof per representative for inspectional work, and $10.00 per hour or fraction thereof per representative for laboratory and analytical work.

B. Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, after compliance has been made with the provisions of subparagraphs (1), (2), and (3) of paragraph A hereinabove set forth, smoked chubs or any other smoked fish which contain DDT, including derivatives thereof, in an amount which exceeds the level of 5 parts per million, or which contain dieldrin.

C. Causing chubs and any other fish, while being held for sale after shipment in interstate commerce, and after com-

pliance has been made with the provisions of subparagraphs (1), (2), and (3) of paragraph (A) hereinabove set forth and which contain DDT, including derivatives thereof, in an amount which exceeds the level of 5 parts per million, or which contain dieldrin, to be prepared, packed and distributed as smoked fish.

That a Temporary Restraining Order be granted, after plaintiff has given notice to the defendants or their attorney, restraining the defendants and their officers, agents, servants, employees, representatives, and all other persons in active concert or participation with them or any of them, for 10 days, as herein prayed, since immediate and irreparable injury and damage will result to the plaintiff.

That the defendants, and their officers, agents, servants, employees, and representatives, and all persons in active concert or participation with them or any of them be enjoined and restrained as herein prayed during the pendency of this action; and that the plaintiff be granted judgment for its costs herein and for such other and further relief as to the Court may seem just and proper.

.....
UNITED STATES ATTORNEY
Attorney for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff v. VITA FOOD PRODUCTS OF ILLINOIS, INC., a corporation, and LAWRENCE T. SCHWEIG, an individual, Defendant	No. 70C 2246

ANSWER

Now come Vita Food Products of Illinois, Inc. ("Vita Food") and Lawrence T. Schweig ("Schweig"), hereinafter collectively called defendants, by their attorneys, and in answer to the plaintiff's complaint state as follows:

1. Paragraph 1 of the complaint reads as follows:

> 1. This proceeding is brought under Section 302(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 332(a)], hereinafter referred to as "the Act", which section specifically invests the several United States District Courts with jurisdiction to enjoin and restrain violations of Section 301 of the Act [21 U.S.C. 331].

Defendants admit that this proceeding purports to be brought under 21 U.S.C. 332(a) and that said statute confers jurisdiction upon this court to enjoin and restrain violations of 21 U.S.C. § 331. Defendants deny, however, that they have violated 21 U.S.C. § 331, or any other section of the Federal Food, Drug and Cosmetic Act.

2. Paragraph 2 of the complaint reads as follows:

> 2. The defendant, Vita Food Products of Illinois, Inc., is a corporation organized and existing under the laws of the State of Illinois, and trading and doing business at 2222 West Lake Street, Chicago, Illinois, within the jurisdiction of this Court.

Defendants admit the allegations of paragraph 2.

3. Paragraph 3 of the complaint reads as follows:

> 3. The defendant, Lawrence T. Schweig, an individual, is vice-president of said corporation and performs his duties as such at Chicago, Illinois, within the jurisdiction of this Court.

Defendants admit the allegations of paragraph 3.

4. Paragraph 4 of the complaint reads as follows:

> 4. The defendants have been and are now engaged in receiving after shipment in interstate commerce, articles of food consisting of fish known as chubs and containing the chemical substances, DDT, derivatives of DDT, and dieldrin, in preparing said chubs as smoked chubs, and in packing and distributing said smoked chubs for human consumption.

Defendant Schweig denies each allegation of paragraph 4, insofar as that paragraph purports to apply to him individually. Both defendants admit, however, that defendant Vita Food has been and is now engaged in receiving after shipment in interstate commerce articles of food consisting of fish known as chubs, and preparing said chubs as smoked chubs and in packing and distributing said smoked chubs for human consumption. Defendants deny, however, that defendant Vita Food has been or is now engaged in receiving after shipment in interstate commerce chubs containing the chemical substances DDT, derivatives of DDT, and Dieldrin.

5. Paragraph 5 of the complaint reads as follows:

> 5. Said smoked chubs when distributed as aforesaid are adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) in that they contain food additives, namely, DDT, derivatives of DDT, and dieldrin, which are unsafe within the meaning of 21 U.S.C. 348(a) in that said additives and their use and intended use are not in conformity with a regulation or exemption issued pursuant to 21 U.S.C. 348(a) since the total amount of DDT and its derivatives present in said smoked chubs is at a level in excess of the interim limit of 5 parts per million which was established by the Food and Drug Administration for all fish pursuant to an announcement to the public on April 22, 1969 and which is still in effect, and since the presence of dieldrin in smoked fish is not permitted by any regulation or exemption issued pursuant to 21 U.S.C. 348(a).

Defendants deny each allegation of paragraph 5.

6. Paragraph 6 of the complaint reads as follows:

> 6. Said defendants violate 21 U.S.C. 331(a) in that they introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce smoked chubs which are adulterated within the meaning of 21 U.S.C. 343(a)(2)(C) as aforesaid.

Defendants deny each allegation of paragraph 6.

7. Paragraph 7 of the complaint reads as follows:

> 7. Said defendants violate 21 U.S.C. 331(k) in that they cause chubs, while held for sale after shipment in interstate commerce and containing DDT, derivatives of DDT, and dieldrin as aforesaid, to be prepared, packed and distributed as smoked chubs, which acts

result in said smoked chubs being adulterated within the meaning of 21 U.S.C. 342(a)(2)(c) as aforesaid.

Defendants deny each allegation of paragraph 7.

8. Paragraph 8 of the complaint reads as follows:

8. Said defendants are well aware that their activities are in violation of the Act. The defendants were warned by a hearing held pursuant to 21 U.S.C. 335 on September 16, 1969, in regard to the interstate shipment of smoked chubs which were found to contain DDT, and derivatives thereof in excess of the permitted amount of 5 parts per million. The defendants have also been warned of subsequent interstate shipments of smoked chubs which contained dieldrin and excessive amounts of DDT and its derivatives, and of the receipt of fresh chubs which contained dieldrin and excessive amounts of DDT and its derivatives. Despite such warnings the defendants continue to distribute smoked chubs which are adulterated as hereinbefore alleged.

Defendants deny each allegation of paragraph 8.

9. Paragraph 9 of the complaint reads as follows:

9. Plaintiff is informed and believes that unless restrained by this Honorable Court said defendants will continue to cause said smoked chubs to be adulterated as aforesaid while held for sale after shipment in interstate commerce and to introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce said smoked chubs adulterated as aforesaid.

Defendants deny each allegation of paragraph 9.

Wherefore, both defendants respectfully request that this cause be dismissed with prejudice, and that both defendants be awarded their costs herein.

VITA FOOD PRODUCTS OF ILLINOIS, INC.
LAWRENCE T. SCHWEIG

By PATRICK W. O'BRIEN
Patrick W. O'Brien

WATSON B. TUCKER
Watson B. Tucker

231 South LaSalle Street
Chicago, Illinois 60604

Their Attorneys

Of Counsel:
Mayer, Brown & Platt

CERTIFICATE OF MAILING

The undersigned hereby certifies that on November 12, 1970 he served a copy of the foregoing Answer by mailing same, with postage fully prepaid, to William J. Bauer (attention R. J. Krajcir), United States Attorney.

WATSON B. TUCKER
Watson B. Tucker

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. VITA FOOD PRODUCTS OF ILLINOIS, INC., a corporation, and LAWRENCE T. SCHWEIG, an individual, Defendants.	No. 70 C 2246

MEMORANDUM OPINION AND ORDER

The proceedings upon which the following opinion is rendered are based upon a Complaint for Injunction filed by the United States of America under Section 302(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 332(a), (hereinafter referred to as the Act), which invests this Court with jurisdiction to enjoin and restrain violations of Section 301 of the Act, 21 U.S.C. 331.

Defendant, Vita Food Products of Illinois, Inc., is an Illinois corporation. Defendant, Lawrence T. Schweig, is vice-president of the corporation.

The government alleges that the defendant receives after shipment in interstate commerce, articles of food consisting of fish, known as chubs, and distributes them for human consumption and that these chubs are adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) in that they contain food additives, namely the chemical substances, DDT, derivatives of DDT, and dieldrin, which are unsafe within the meaning of 21 U.S.C. 348(a). The government further alleges that the above-named additives and their use and intended use are not in conformity with a regulation or exemption issued pursuant to 21 U.S.C. 348(a), "since the total amount of DDT and its derivatives present in said

smoked chub is at a level in excess of the interim limit of 5 parts per million which was established by the Food and Drug Administration for all fish pursuant to an announcement to the public on April 22, 1969 and which is still in effect, and since the presence of dieldrin in smoked fish is not permitted by any regulation or exemption issued pursuant to 21 U.S.C. 348(a)."

The government contends that the defendants violate 21 U.S.C. § 331(a) in that they introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce smoked chubs which are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C) and that defendants violate 21 U.S.C. § 331(k) in that they cause chubs, while held for sale after shipment in interstate commerce and containing the above-named chemical substances, to be prepared, packed and distributed as smoked chubs, which acts result in the smoked chubs being adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C).

A hearing was held pursuant to 21 U.S.C. § 335 on September 16, 1969 regarding the interstate shipment of smoked chubs which were alleged to contain the aforementioned chemical substances in excess of the amounts of 5 parts per million of DDT or derivatives or which contained dieldrin in excess of .3 ppm.

I

In effect, the government's theory is that the chubs involved herein are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C) because DDT and dieldrin are "food additives" under the Act and second since "their use and intended use are not in conformity with a regulation or exemption" they are "unsafe" as a matter of law under the terms of 21 U.S.C. § 348(a).

Defendants' position is "that any traces of DDT and dieldrin in its smoked fish are not food additives within the Act," and that the government's mode of procedure "seri-

ously perverts the elaborate statutory scheme established by Congress to ensure the safety of food and food additives and that defendants are not now and have not in the past sold any 'adulterated' smoked fish."

Defendants contend that government has tried to establish adulteration as a matter of law because it is unable to establish adulteration as a matter of fact and in so doing has ignored the statute.

21 U.S.C. § 342(a)(1) states as follows:

> "A food shall be deemed adulterated—if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of Section 346 of this Title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 346(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of Section 348 of this title. . . ."

21 U.S.C. § 348(a) states as follows:

> "A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title, unless—
>
> (1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant

> to subsection (i) of this section; or (2) there is in effect, and its use or intended use are in conformity with, a regulation issued under the section prescribing the conditions under which such additive may be safely used. While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342(a) of this title."

DDT is a chemical pesticide which has been used since the early 1940's to control mosquitoes and other pests. Recently, the use of DDT has been reduced by approximately 80% in the United States (tr. 219) and as of January 1, 1972, due to an order of the Environmental Protection Agency, the use of DDT will be almost eliminated. DDT and its derivatives are found in virtually all living tissue. Studies show that these concentrations (8-10 parts per million) in man (tr. 180) are decreasing (tr. 863-66; 1185-86).

Dieldrin is a far more mysterious substance than DDT although like DDT it finds its way into certain organisms. The most that can be said of dieldrin at this juncture is that its effect has not been fully demonstrated.

On April 22, 1969, a "guideline" characterizing 5 ppm as the maximum amount of DDT permissible in fish shipped in interstate commerce was issued in the form of a press release by the F.D.A. In part the release stated:

> "Residues of DDT (including derivatives) in fish shipped in interstate commerce will be limited to 5 parts per million (ppm) under an interim guideline announced today by the Food and Drug Administration.
>
> "The interim limit has been established primarily because of high residues of DDT and its derivatives found in coho salmon from Lake Michigan.

"This guideline is intended to protect the public from excessive levels of DDT in fish while a full scientific review is completed," Food and Drug Commissioner Herbert L. Ley, Jr., M.D. explained "It also gives the fishing industry a specific standard. Fish carrying residues higher than 5 ppm will be subject to seizure.

"The F.D.A. has asked the National Academy of Sciences—National Research Council to nominate a panel of experts to carry out the review of DDT residues in fish. The 5 ppm interim limit may be changed as the result of that study, Dr. Ley said."

In ruling on the statutory basis for the F.D.A.'s authority to issue its interim enforcement guideline the Court in United States v. City Smoked Fish Co., et al. (E.D.Mich., Memo.Op. 33669, pg. 6, 1970) said:

"Plaintiff concedes that this guideline is neither a 'regulation' which the Act empowers it to issue, nor any other species of administrative rule recognized by any relevant or pleaded statute. This guideline is not published in the Code of Federal Regulations, nor apparently in any other published compilation of administrative rules.

"Since there is no statutory authority to issue such an interim enforcement guideline, it follows that defendants' violation of law, if any, must be of the statute itself, in this case The Food, Drug and Cosmetic Act."

The Court therein found such violation of the statute. However, I find myself in disagreement with that decision and instead find that DDT and dieldrin are not "food additives" within the meaning of the Food, Drug and Cosmetic Act of 1939.

I have come to this conclusion after a careful analysis of the statute, the 1959 "Food Additives Amendment" and its legislative history and purpose.

I find it necessary to quote at this point from that legislative history:

> " • • • This bill, if enacted, will require the processor who wants to add a new and unproven additive to accept the responsibility now voluntarily borne by all responsible food processors of first proving it to be safe for ingestion by human beings.
>
> " • • •
>
> "The second flaw in existing law which has proved detrimental to consumers, the processors, and to our national economy and which this bill seeks to remove is a provision which has inadvertently served to unnecessarily proscribe the use of additives that could enable the housewife to safely keep food longer, the processor to make it more tasteful and appetizing, and the Nation to make use of advances in technology calculated to increase and improve our food supplies. Your committee agrees with the Food and Drug Administration that existing law should be changed to permit the use of such additives as our technological scientists may produce and which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted by the Food and Drug Administration as safe." Senate Report No. 2422, 85th Cong., 2d Sess., 3 U.S.Code Cong. & Admin. News. p. 5301 (1958).

Thus, the purpose of the Amendment was two-pronged; to permit the use of food additives in safe quantities but only after tests for safety conducted before the food in which those additives are used is introduced into commerce.

Section 348 provides an elaborate procedure for evaluating the safety of "food additives". Thus, 21 U.S.C. § 348 (b)(1) reads as follows:

> "Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation. . . ."

and contains elaborate procedures that must be adhered to by any person who intends to use a food additive and details the conditions under which such an additive may be safely used.

It is uncontroverted that defendants herein do not actually "add" DDT or dieldrin to its product. The chemicals in question are introduced into the chubs by the environment. In no way have the defendants been accused of nor do they deliberately use the named substances in connection with the preparation of their product.

The Committee reports which accompany the Food Additives Amendment deal with three different categories of "food additives".

> "The legislation covers substances which are added intentionally to food. These additives are generally referred to as 'intentional additives.'
>
> "The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as 'incidental additives.'
>
> "The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food." Senate Rep. No. 2422.

Therefore, it may be seen that neither the "intentional" nor "incidental" category of "food additive" is applicable. It is not an "intentional" additive because there is no allegation that the defendants nor for that matter any other person or corporation add the named chemical substances to the chubs.

Nor may they be considered "incidental" additives because Congress clearly enunciated that only those substances de-

liberately used in the course of the manufacturing or distribution process would be within that category. It is indisputable that any DDT or dieldrin in defendants' chubs result from unintentional circumstances which occur prior to the fish being caught.

The third category of "additives" are "accidental" and the Senate Report states as follows in respect to such additives:

> "On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as 'accidental additives', since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable."

I find myself in agreement with defendants that if, indeed, DDT and dieldrin traces found in fish are to be considered "additives" in any sense, they must clearly be considered "accidental" ones and as such not a "food additive" under the Act. Thus, I am in disagreement with the government's contention that "as components of the defendants' chub, residues of DDT and dieldrin are incidental food additives governed by the food additive provisions of the Act." (Govt.'s post-tr. brief, pg. 30).

One of the government's witnesses Dr. Frederick Coulston stated that DDT's presence in the chubs is 'accidental' (tr. 245). Dr. Coulston testified as follows:

> Q. Do you know, sir, from your studies and through your group, what the best thinking is as to how the DDT got there? (Into fish that are swimming in lakes).
> A. Well, of course nobody rightly knows exactly how it got there. We can only suppose that the use of the

> DDT in spraying for environmental control of insects or in use on crops in the soil, eventually washed down into the rivers and then into the lakes * * *" (tr. 207).

Thus, the chemical substances DDT and dieldrin are not ones intended for use in "producing, manufacturing, packing, processing, transporting, or holding food." Congress was most explicit in its delineation of what constitutes an "intentional" or "incidental" additive.

21 U.S.C. § 321(s) defines "food additive" and expressly excludes—

> "(1) a pesticide chemical in or on a raw agricultural commodity; or
>
> "(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity * * *."

A case on point is one cited by defendant, United States v. Bodine Produce Co., 206 F.Supp. 201, 210 (D.C. Ariz. 1962) in which the Court stated that the DDT found in lettuce was not a "food additive":

> "* * * By the Food Additive Amendment in 1958 * * * Congress tackled the problems of food additives in processed foods in depth. It drew a sharp line between the Food Additives Amendment and the Pesticide Chemicals Amendment. Thus in the definition of "food additive" it excluded pesticide chemicals in or on raw agricultural commodities. * * *"

In Environmental Defense Fund v. United States, 138 U.S.App.D.C. 391, 428 F.2d 1083 (1970), the Court stated:

> "* * * the statute (21 U.S.C. § 321(s)) explicitly excludes pesticide chemicals from the definition of the terms 'food additive" and 'color additive'."

The government has attached as Ex. D to its Trial Memorandum the ruling in U. S. v. City Smoked Fish, *supra,* in which the Court found:

> "It further appears that DDT found in *raw* chubs is a pesticide chemical and not a food additive within the meaning of the Act. However, the Court concludes that DDT found in *smoked* chubs is a 'food additive', since the chubs are no longer in their raw or natural state as required by the Act."

I cannot agree. 21 U.S.C. § 342(a) states that a "pesticide chemical" remains a "pesticide chemical" within the meaning of the Act even after the "raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling."

For the above stated reasons, I find that any traces of DDT or dieldrin found in defendants' chubs cannot be labeled a 'food additive' within the meaning of the Food, Drug and Cosmetic Act of 1938.

II

The next issue to be resolved is that of whether or not the chubs in question fall within the purview of 21 U.S.C. § 342 (a)(1), *supra*, a portion of which states:

> "A food shall be deemed to be adulterated—If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

The government has alleged as follows:

> "It should be noted that smoked chubs containing residues of DDT, its derivatives or dieldrin in excess of the enforcement guidelines need not be proven injurious to health to be adulterated under the Act. In a long line of cases, the federal courts have held that foods may be adulterated regardless of whether they

are injurious to health, unless the particular statutory definition of adulteration expressly requires the Government to prove such injury (citing cases). Since 21 U.S.C. § 342(a)(2)(C) does not require such proof, no injury to health need be shown to establish the adulteration alleged in this case." (Govt's Tr. Memo., p. 20).

However, having found that 21 U.S.C. § 342(a)(2)(C) is not applicable, I find that injury to health must be shown in order for the government to prevail. The testimony on this issue was diverse and interesting but in the final analysis not as illuminating nor as definitive as might have been hoped.

Dr. Frederick Coulston, a toxicologist and one of the government's witnesses testified as to rumors that DDT might be a carcinogen:

"But its the uncertainty. I can only state that I know of no harm to man, human beings, from DDT even in larger amounts than five parts • • •." (Tr. 218).

Professor Rolf Hartung, another government witness testified as follows:

"There is at least one suggestive study by Poland who looked again at a series of pesticide formulators and reported that those people who had received 20 times the normal background level of pesticides did exhibit a slight increase in the rate in which they would metabolize these drugs.

• • •

"Now this does not in any way imply safety either. The reason it doesn't imply harmfulness is because the effects are very subtle and we cannot make an easy judgment as to whether this is permanently hurting a person or not. I am dubious that it would personally hurt a person." (Tr. 297).

A short time later in the trial Professor Hartung stated:

> "If we want to look for any evidence whatever as to what might be happening for man at normal types or close to normal types of dosage, we are very hard put." (Tr. 299).

Dr. William Deichmann, an eminent toxicologist, testified in behalf of the defendant and stated during the trial that counsel for the government had telephoned him and

> " • • • told me that the Vita Food Company had been selling smoked fish which contained 7 or 8 parts per million DDT, and whether I would speak for Food and Drug Administration, since the permissible limit in smoked fish is 5 parts per million, and the primary issue was whether I could make the statement that the ingestion of smoked fish containing 7 or 8 parts per million is injurious to health.
>
> "Q. And what did you say, sir?
>
> "A. I told Mr. Raubicheck (government counsel) that if it is a question of whether the food company is guilty of exceeding the concentration, if that is the question, that I must agree that 7 or 8 is more than 5, and on that basis I would say they would be guilty, but if it is a question of health hazard of a concentration of 8 parts per million, that I couldn't support that, and for that reason I declined to testify for Food and Drug, and I wrote to Mr. Raubicheck a letter to that effect." (Tr. 844-45).

When asked his opinion as to the chronic toxicity of residues of DDT in human beings Dr. Deichmann responded:

> "I could refer you to the studies that have been done where the concentrations, the retention rates in human beings, have been very much higher than those in the general population without any effect that the investigators and physicians tried to find and did not find." (Tr. 807).

In response to the question of whether he knew of any disease in humans attributable to DDT the witness replied:

> "I have introduced this word on two occasions (DDT-itis), and I made the statement that there is no record of any DDT-itis in this country or any other country. . . ." (Tr. 807).

Again Dr. Deichmann testified:

> "Nowhere in the world does this compound, and I am referring to DDT, present an 'imminent hazard' to public health—." (Tr. 852).

Thus, I cannot on the basis of the evidence tendered during the course of this trial unequivocably state that DDT is a known health hazard to man.

III

A great portion of the trial revolves around the issue of the reliability of the test methodology used by the government to prove that the samples of Vita's chubs involved herein contained DDT concentrates in excess of 5 ppm. The government's test method is referred to as the "AOAC" method. Although I shall not go into a detailed analysis of the testing procedures I should like to note the following information that was gleaned from the trial testimony.

No method of testing has been proven to be absolutely reliable. Certain discrepancies that were raised during trial and in defendant's post-trial brief have led me to conclude that the AOAC method is capable of distinguishing between concentrations of DDT in the area of 4 to 9 ppm. Thus, there is always the possibility of a margin of error and I must hold that the AOAC method, when left to be followed by testers provided by food processors in all cases and utilized by government testers only in spot checking on the continuous batch upon batch testing to be performed by the food processors, is incapable of that degree

of accuracy which ought to exist to support a court judgment enjoining a food processor from proceeding on in the industry.

Since September 1971, the American Meat Institute Laboratory (AMI) has been hired by Vita to analyze its chubs for pesticides, using the AOAC method. The AMI Laboratory also analyzes each of the samples which formed the foundation for the case herein. Its analysis showed substantially lower results than did the comparable analysis performed by the FDA chemists. Four of the seven AMI analyses showed readings below 5 ppm and the highest of those above 5 ppm read 5.35. There are numerous other examples of differences between the various methods of testing. Differences in results tended to reflect differences between individual chemists performing the tests.

The concept "absolute reliability", like the phrases "unimpeachable preciseness" and "perfect certainty", is repugnant to the scientific mind. The most that should be looked for is "sufficient reliability"—reliability to a degree sufficient for the purpose to be served. The purpose to be served here is not served when the acknowledged degree of exactness has a coefficient of error of plus or minus 25%, and when various tests of the same samples with the same procedures performed by equally qualified persons result in readings varying over a range of one hundred percent.

From all the relevant data one fact stands out. It is that science has not developed a system which is sufficiently reliable. The AOAC's method is not sufficiently reliable for me to find by the greater weight of the evidence and as a controlling fact that the chubs sampled by FDA in April 1972 contained DDT concentrations in excess of 5 ppm.

There is in this case uncontradicted evidence tending to show that the level of Lake Michigan chubs generally is less than 5 ppm. Mr. Bernard Lorant, a chemist, testified that based upon all of the test results in evidence (FDA's, AMI's, NMFS, and those of WARF) (Def. Ex. 29) the incidence of DDT and its analogs in Lake Michigan chub are at or below 5 ppm. (Tr. 1202-03).

IV

In summary, I find that 21 U.S.C. § 342(a)(2)(C) is not applicable since DDT, derivatives of DDT and dieldrin found in Vita's smoked chubs are not "food additives" under the Act. I find that DDT, derivatives of DDT and dieldrin as found in Vita's smoked chubs are not a known health hazard within the meaning of 21 U.S.C. § 342(a)(1). I find that the test method to be used by processors of smoked chub is not sufficiently precise for a finding of fact that the chubs sampled in April 1972 contained DDT concentrations in excess of 5 ppm.

It should be made crystal clear that these findings do not open the gate to an area of abandonment of concern on the part of processors of food. Neither do they restrain the Food and Drug Administration from pursuing a severe program of monitoring processors of smoked fish in its efforts to keep out of interstate commerce food that constitutes a known health hazard. I have been presented in this case just one matter and my findings are technical ones. By the greater weight of the evidence and by the applicable law the allegations of the complaint against these defendants have not been sustained.

This Memorandum Opinion shall constitute my findings of fact and conclusions of law.

ORDER

Wherefore, it is ordered, adjudged and decreed that judgment with costs ought be and the same hereby is entered in favor of the defendants and against the plaintiff.

ENTER:

JAMES B. PARSONS

JAMES B. PARSONS
United States District Judge

DATED: February 14, 1973

IN THE UNITED STATES COURT OF APPEALS
For the Seventh Circuit

No. 73-1008
UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

EWIG BROS. CO., INC., a corporation, and EUGENE W. EWIG, an individual,
Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Wisconsin.

No. 71-C-158

MYRON L. GORDON
Judge.

No. 73-1454
UNITED STATES OF AMERICA,
Plaintiff-Appellant,

v.

VITA FOOD PRODUCTS OF ILLINOIS, INC., a corporation, and LAWRENCE T. SCHWEIG, an individual,
Defendants-Appellees.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

N. 70-C-2246

JAMES BENTON PARSONS, *Judge.*

ARGUED JANUARY 7, 1974 — DECIDED AUGUST 28, 1974

Before HASTINGS, *Senior Circuit Judge*, and STEVENS and SPRECHER, *Circuit Judges.*

STEVENS, *Circuit Judge.* There are two ways to state the principal question presented by these appeals. Narrowly, the issue is whether residues of DDT and dieldrin in smoked chubs are "food additives" within the meaning of § 201(s) of the Federal Food, Drug and Cosmetic Act.[1]

[1] Section 201 of F.D.C.A., enacted as part of the "Food Additive Amendment of 1958," 72 Stat. 1784, is codified as 21 U.S.C. § 321. The definition of "food additive" reads as follows:

> (s) The term "food additive" means any substance the intended use of which results or may reasonably be expected

A somewhat more disturbing way to state the same question is whether all of the fish in the Great Lakes are "adulterated" as a matter of statutory definition.[2] If they are, the Administrator[3] may have, at least for the present, vir-

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to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended; or

(5) a new animal drug.

[2] Section 402 of F.D.C.A., 21 U.S.C. § 342, defines adulterated food. The provisions of subparagraphs (a)(2)(B) and (a)(2)(C), which pertain, respectively, to pesticide chemicals on raw agricultural commodities and to food additives are relevant here; they are quoted in n. 11, *infra*.

[3] Enforcement responsibility presently resides in the Administrator of the Environmental Protection Agency. The respective functions of the Secretary of H.E.W., the Secretary of Agriculture, and the Administrator, and the transfers effected by Reorganization Plan No. 3 of 1970, effective as of December 2, 1970, are outlined in *United States* v. *Goodman*, 486 F.2d 847, 848-849 (7th Cir. 1973).

tually unbridled power to eliminate all such fish from our food supply. We therefore attach special importance to the additional questions presented in the *Vita Food* appeal. That appeal, unlike the *Ewig Bros.* appeal,[4] requires us to consider the legal significance of an "interim guideline" announced in a press release on April 22, 1969, as well as the district court's findings that the testing methods used by the government's experts were not sufficiently reliable to demonstrate that Vita's smoked chubs contained more DDT than the guideline permits.

A total ban on the future use of DDT would not resolve the problem presented by this case. Although the levels of

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[4] The *Ewig Bros.* case was brought as a companion to complaints filed against five other defendants which distributed raw chubs, as opposed to the smoked chubs distributed by Ewig. In all six cases, the parties stipulated that the quantity of DDT in the chubs exceeded the informal guidelines, and, in the five raw chub cases, that DDT was a "pesticide chemical" and that the fish were "raw agricultural commodities" within the meaning of § 201 of F.D.C.A. (see 21 U.S.C. § 321(q) and (r)). In all cases Judge Gordon rejected the defendants' argument that the Administrator was required by statute to establish tolerance limits for DDT in fish before he could claim that the presence of DDT residues resulted in adulteration. In the *Ewig* case, Judge Gordon also held that DDT in the processed chubs is a food additive. He entered permanent injunctions in all six cases.

On September 29, 1973, we affirmed the judgments in the five cases involving raw chubs and entered an order holding the *Ewig* appeal for decision with *Vita Food*. See *United States* v. *Goodman*, 486 F.2d 847, 849 n. 10. In that case we held that the Administrator is not required to establish by regulation permissible tolerances of DDT and its derivatives before initiating enforcement proceedings or obtaining injunctive relief in such a proceeding. Judge Sprecher's opinion in that case describes the enforcement guideline, the evidence of growing national concern over DDT content in fish, and portions of the statutory scheme which could have been invoked by the raw chub distributors to establish tolerances for DDT residues in their products. The only contention raised by Ewig Bros. on this appeal is that Judge Gordon erroneously held that DDT residues in smoked chubs are a "food additive."

DDT contamination are declining, we must assume that the chemical, or its derivatives, will survive as an ingredient of all or most foods for some time.[5]

Scientists seem to agree that if the DDT level is high enough, the food should not be consumed by man and, conversely, if the amount is sufficiently small, ingestion of DDT may be harmless. Danger levels have not been precisely defined. The record demonstrates, however, that in fish levels in the range of 5 parts per million are neither (a) generally recognized among qualified experts as safe,[6] nor (b) demonstrably injurious to health or unfit for human consumption.[7] At the levels disclosed by the record before us, the effect on human health is somewhat uncertain.

Unquestionably DDT is a "pesticide chemical" as that term is defined in § 201(q) of F.D.C.A. See 21 U.S.C. § 321(q). Pursuant to statutory procedures, tolerances have been established for its use in or on various raw agricultural commodities, including fruits, vegetables, and meat.[8] Such foods may therefore contain DDT within the prescribed tolerance limits without being "adulterated." It does not follow, however, that a level which is either safe or unsafe for one food would be equally safe or unsafe for another

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[5] Concentration levels vary in different kinds of tissue. It is higher in Great Lakes fish than in most other foods, and especially high in the fat tissue and in fish caught in certain parts of Lake Michigan.

[6] See also *United States* v. *Goodman, supra,* 486 F.2d 851-853.

[7] The government made no effort to establish adulteration as defined in subparagraphs (a)(1) or (a)(3) of § 402. See 21 U.S.C. § 342.

[8] See 40 C.F.R. § 180.147. Thus, for example, a tolerance of seven parts per million has been established for a number of items including "fat of meat from cattle, goats, hogs, horses, and sheep . . . spinach, squash, . . ." and a tolerance of only one part per million for a number of other items, such as artichokes, peanuts and radishes. Tolerances have also been established for dieldrin. 40 C.F.R. § 180.137.

food.[9] With respect to the foods for which DDT tolerances have been set, it is reasonable to infer that the rule-making process may have been invoked either by the FDA itself, by manufacturers or distributors of the pesticide, or by farmers or producers who are interested in using DDT as a pesticide. Fishermen, however, have never had any interest in using or selling DDT themselves; its presence in the environment is a condition of their work—and also of the business of distributing or processing fish—for which they are not responsible and which they have no interest whatsoever in perpetuating. In short, unlike farmers and pesticide salesmen, they have never had any interest in adding DDT to the environment or to the food supply. From their point of view, it is not an item which is added to their products; it is a natural component of the fish before it is caught, let alone processed.

In this case the government's claim that defendants' chubs are "adulterated" is not predicated on a claim that the particular fish defendants sell contain a poisonous substance or are otherwise unfit for food pursuant to either subparagraph (1) or subparagraph (3) of § 402 of the F.D.C.A.[10] Under those subparagraphs the government

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[9] Different foods are, of course, consumed in differing quantities and absorbed into the body under differing conditions. The elimination of fat by consuming only fillet of the fish, for example, may significantly reduce the intake of DDT.

[10] Sections 402(a)(1) and 402(a)(3), codified in 21 U.S.C. § 342, provide:

> A food shall be deemed to be adulterated—(a) Poisonous, insanitary, etc., ingredients.
>
> (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;
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> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

would have the burden of proving that the fish are actually harmful to man. Instead, the government's claim is predicated on § 402(a)(2)(C),[11] under which it need only prove that "such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use . . . ." § 201 (s) of the F.D.C.A., 21 U.S.C. § 321(s).[12]

It is the government's position that a fair analysis of the statutory scheme Congress has enacted, including the allocation of decision-making responsibility between the agency and the judiciary, justifies proceeding under this section. For if, as the government contends, DDT is a food additive, the Food and Drug Administration may itself decide when products containing quantities of DDT should be re-

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[11] That section, also codified in 21 U.S.C. § 342, provides that a food shall be deemed adulterated

> (C) if it is, or if it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity
>
> . . . .

Subsection (a)(2)(B) provides a similar standard:

> (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title . . . .

[12] The government clearly met that burden in this case.

moved from public consumption, without having to rely upon the decisions—possibly inconsistent with one another —of different federal judges determining danger to health under §§ (a)(1) and (a)(3) on a case-by-case basis.

The question, then, is whether DDT and dieldrin in defendants' processed fish are "food additives" within the meaning of § 201(s).

I.

We have recently identified the principal purposes of the food additive amendment of 1958.[13] Neither the purpose to establish a procedure for premarketing clearance of untested food additives, nor the intent to permit the evaluation of such products to encompass a consideration of their benefits, as well as their potential for harm, seems directly relevant to the question before us. Rather, we are concerned with products which, at least primarily, were intended to be regulated as pesticide chemicals rather than as food additives. It is therefore appropriate to review the development of the pesticide chemical legislation enacted in 1954 as well as the food additive amendment itself.

Prior to 1938 a poisonous substance added to a food during processing would not cause adulteration unless the government could prove that the food itself, as opposed to the added substance, was unsafe.[14] After 1938, however, the statute has focused attention on the character of the added substance. Section 406 of the 1938 Act prohibited the use of poisonous or deleterious substances unless industry demonstrated that the substance was required for processing and also persuaded the Administrator[15] to issue a tolerance regulation permitting use in amounts below a specified level. Pending the promulgation of such a tolerance regulation, the addition of any poisonous or deleterious substance—even traces which could not possibly affect the

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[13] See *Continental Chemiste Corp.* v. *Ruckelshaus*, 461 F.2d 331, 340-341 (1972).

[14] *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399.

[15] See n. 3, *supra*

safe character of the end product—constituted adulteration as a matter of law.[16] The "per se" approach adopted in 1938 placed the burden of proving safety upon industry and, as a matter of procedure, mandated marketing delays until after formal administrative review could be completed.

Although the 1938 Act authorized the promulgation of regulations limiting the amount of pesticide residues that remain in or on food (since such chemicals were obviously "poisonous or deleterious"), only one such regulation was actually issued during the subsequent 15-year period. The absence of such formal tolerance regulations was attributable, in part, to the expense and complexity of the rule-making procedure and, in part, to the required showing that use of the added substance be essential or unavoidable during processing.[17] Instead of employing the statutory pro-

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[16] To soften the impact of a rule which appeared to establish that food containing even traces of a deleterious substance, that could not possibly affect the safety of the final product, some courts read the *de minimis* qualification which had existed under the previous statute, *United States* v. *133 Cases of Tomato Paste*, 22 F.Supp. 515 (E.D. Pa. 1938), into the new statute. See *338 Cartons, More or Less, of Butter* v. *United States*, 165 F.2d 728 (4th Cir. 1947). See also *United States* v. *484 Bags, More or Less*, 423 F.2d 839, 841 n.1 (5th Cir. 1970).

[17] The procedure before the 1954 amendments was described in the Senate Report as follows:

> Under existing law, added poisonous and deleterious substances—and most pesticide chemicals fall in this class—must be kept out of foods unless they are required in production or cannot be avoided by good manufacturing practice. When such a substance is required in production—as many pesticide chemicals are required in growing agricultural crops—a tolerance may be established by the Secretary of Health, Education, and Welfare, but only after a formal public hearing. Detailed findings of fact and conclusions must be made by the Secretary as to the required use of the pesticide and the residue levels that may safely be tolerated.

Sen. Rep. No. 1635, 83rd Cong., 2d Sess., 2 U.S. Code Cong. & Admin. News 2627.

cedure, the F.D.A. exercised practical control by means of an extra-legal system of unofficial and informal tolerances.[18]

The pesticide chemical amendment of 1954 was adopted to enable industry to make effective use of these poisonous products, even when not absolutely necessary, and to simplify, expedite, and improve the tolerance rule-making procedure[19]—as well as to remove uncertainty from the law.[20]

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[18] This system was apparently authorized by § 306 of the 1938 Act, codified as 21 U.S.C. § 336, which provides:

> Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

Some of the difficulties with this system are canvassed in Judge Frank's dissenting opinion in *United States* v. *449 Cases, Containing Tomato Paste*, 212 F.2d 567, 575-581 (2d Cir. 1954).

[19] The primary purpose of the bill is to assure greater protection of the public health by improving, simplifying, and speeding up the procedure under the Federal Food, Drug, and Cosmetic Act, for regulating the amount of residue which may remain on raw agricultural commodities after use of pesticide chemicals.

* * *

> A primary objective in drafting the bill was to develop legislation that would provide for prompt administrative action to permit effective use of pesticide chemicals without hazard to the public health; legislation that would be safe for consumers and practical for producers.

Sen. Rep. No. 1635, 83rd Cong., 2d Sess., *supra* n.17, at 2627.

[20] . . . [C]ontrol . . . exercised through unofficial and informal tolerances . . . [, since] the necessary tolerances have not yet been issued . . . has been responsible for uncertainty under the law. It has handicapped the Government in enforcing the law, the grower in complying with the law, and the pesticide manufacturer and Federal and State agencies in discharging their responsibility for advising and making recommendations to the grower with respect to the use of pesticide chemicals.

Sen. Rep. 1635, 83rd Cong., 2d Sess., *supra* n.17 at 2627.

The 1954 Act created a category of added poisonous substances known as "pesticide chemicals" and authorized their use in or on "raw agricultural commodities" unless they were "unsafe" within the meaning of a newly enacted § 408.[21] That section provided that every pesticide chemical was "unsafe" unless exempted by the Secretary or used within a tolerance limit prescribed by the Secretary. Except insofar as courts would continue to read a *de minimis* exception into the new requirements,[22] and except insofar as the Administrator would decline to prosecute minor violations, every pesticide chemical was unsafe and caused adulteration unless and until it was the subject of a tolerance and thereafter used in conformity with the tolerance. As a matter of practice, a large number of tolerances were promulgated; the use of DDT and dieldrin was thereafter lawful as long as residues of these pesticides on raw agricultural commodities did not exceed specified limits.[23]

Just as the pesticide chemical amendment in 1954 created a new category of added substances which automatically caused adulteration unless exempted or used in conformity with an established tolerance, so did the 1958 amendment create still another new category—food additives—which also, by definition, caused adulteration unless exempted or used within a prescribed tolerance. Section 402, describing adulterated food, was amended to include any food which bears or contains an "unsafe" food additive, and every such additive was deemed unsafe unless used in compliance with a tolerance regulation issued under a new § 409.

Thus, congressional efforts to define and regulate adulterated food in the 20 years before 1958 reflected a con-

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[21] This section is codified as 21 U.S.C. § 346a.

[22] See n. 16, *supra*. We have found no case applying or refusing to apply the *de minimis* exception to products containing pesticide chemicals.

[23] See n. 8, *supra*.

sistent desire to rationalize the law by reducing the circumstances in which the F.D.A. must prove actual danger to a quantity of food and by establishing a system of tolerances which will both protect the public and enable industry to operate effectively.

The legislative history of the 1958 Bill indicates concern about the difficulties present when dangerous substances could not be proscribed by per se rules.[24] Since Congress used broad language in order to eliminate such difficulties, we should not construe it narrowly. The language, set forth in full above,[25] defines a food additive as *any* substance, "the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . ." Although Congress was primarily concerned with substances used by a food processor, neither the language nor the history of the 1958 Act limits its application to such substances.[26] The words "the intended use of which" are not confined, as they easily could have been confined, to use in food processing.

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[24] . . . [U]nder existing law the Federal Government is unable to prevent the use in foods of a poisonous or deleterious substance until it first proves that the additive is poisonous or deleterious. To establish this proof through experimentation with generations of mice or other animals may require 2 years or even more on the part of the relatively few scientists the Food and Drug Administration is able to assign to a particular problem. Yet, until that proof is forthcoming, an unscrupulous processor of foodstuffs is perfectly free to purvey to millions of our people foodstuffs containing additives which may or may not be capable of producing illness, debility, or death.

Sen. Rep. No. 2422, 85th Cong., 2d Sess., 3 U.S. Code Cong. & Admin. News 5300.

[25] See n. 1, *supra*.

[26] See the passage from the Legislative History of the Act, quoted in n. 28, *infra*. Note the use of the words "principal examples" in the language which has been emphasized by Vita Foods.

Vita has argued that a process, such as smoking, during which nothing new is added to a food, cannot "transmogrify" a preexisting component of a food into an additive. But whether the food be fish, fruit, or meat, if the component is a pesticide chemical, we think that is exactly what Congress intended.

Although it may seem odd to place the label "additive" on a chemical substance which was a component of the raw product and which is not changed by processing, Congress' choice of that label does not result in any "transmogrification." Before processing, DDT is a "pesticide chemical" on a raw product; after processing, it is an "additive." Since there is no tolerance for DDT on fish, both before and after processing the presence of the DDT causes fish to be adulterated without any proof that it is actually unfit as food. Defendants' contention, if accepted, would result in the anomaly that a chemical such as DDT would adulterate all raw fish, but adulteration of processed fish would be determined on an uncertain case-by-case basis. We conclude that such a construction of the statute is illogical and unacceptable.[27]

This conclusion is confirmed by the full text of the description of products which are "unsafe"—and therefore "adulterated"—because they contain food additives. Sub-

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[27] . . . [T]his court is acutely aware of the fact that it is not the proper body to more narrowly define broad standards in this area so that they can be applied in a particular case. Courts know neither what is necessary for the health of the consuming public nor what can reasonably be expected from the canning industry. Furthermore, this is not a determination that should be made individually for each case on the basis of expert testimony. The Food and Drug Administration should set definite standards in each industry which, if reasonable, and in line with expressed Congressional intent, would have the force of law.

United States v. *1,500 Cases More or Less, Tomato Paste*, 236 F.2d 208, 211 (7th Cir. 1956).

section (a)(2)(C) of § 409 provides that a food is adulterated:

> ". . . if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and *the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;*". 72 Stat. 1784. (Emphasis added.)

Quite clearly the need for the proviso arose from the fact that the definition of a "food additive" is broad enough to include any residue of a pesticide chemical remaining in or on food after processing. Prior to the 1958 amendment only raw agricultural commodities could be adulterated as a matter of law because of the presence of such an added chemical; processed foods were not subject to that risk. Accordingly, prior to 1958, the exemption for such pesticide chemicals used within tolerance limits on raw agricultural commodities was sufficient to avoid the risk of "per se" adulteration for all food subject to that risk. But when the "per se" concept was enlarged to encompass processed food, which might, of course, contain some chemical residue, it became necessary either (a) to make the "food additive" and the "pesticide chemical" categories mutually exclusive, or else (b) to enact a specific proviso

to cover the area of overlap. Congress made the latter choice.

The proviso which Congress enacted avoids the necessity for duplicate tolerances, one covering the use of the chemical on the raw commodity and the second applying to the same chemical after processing. The fact that an express proviso was needed to avoid that consequence confirms our reading of the food additive definition as broad enough to encompass pesticide chemical residues in processed food.

Thus, the tolerance for DDT and dieldrin in or on raw fruits, vegetables, and meat are adequate to avoid adulteration caused by the residues remaining after the foods are processed. Without such tolerances, we think it is clear that the presence of DDT in or on such foods will cause adulteration pursuant to subparagraph (a)(2)(B) in their raw state, and that the same consequence will follow from subparagraph (a)(2)(C) after processing. We are also persuaded that these chemicals have the same impact on fish in the Great Lakes. As long as no tolerances have been established, the raw chubs are adulterated within the meaning of (a)(2)(B) because they contain an unsafe pesticide chemical; after processing, by virtue of (a)(2)(C), the chubs are adulterated because they contain an unsafe food additive. We think this is evident from the entire statutory scheme, the definitional language, and the relevant legislative history.[28] We hold, therefore, that the DDT

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[28] Thus, for example, consider the excerpt from the Senate Report:

LEGISLATIVE HISTORY

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

and dieldrin found in defendants' smoked chubs were "food additives" and, since not protected by any tolerance, the chubs were "adulterated" as a matter of law.

II.

Vita Food argues, in the alternative, that even if DDT and dieldrin are food additives, we should nevertheless affirm because the government failed to prove that residues of these chemicals exceeded the limits specified in the F.D.A. interim enforcement guidelines. In its opinion the

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[28] (Continued)

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

Sen. Rep. No. 2422, 85th Cong., 2d Sess., *supra* n. 24, at 5304.

district court stated that there is never "perfect certainty" in any scientific analysis and that the government's test methods were "not sufficiently reliable for me to find by the greater weight of the evidence and as a controlling fact that the chubs sampled by FDA in April 1972 contained DDT concentration in excess of 5 ppm." 356 F.Supp. 1213, 1221.[29]

Neither party has contested the applicability of the F.D.A.'s 5 ppm enforcement guideline. Nevertheless, it is clear that the government might have argued that the enforcement guideline was merely adopted as an internal standard to determine when it would be appropriate to initiate an enforcement proceeding, and that publication in a Press Release was merely intended to give industry fair notice of its internal standards. By way of analogy, a police department might adopt a policy of not enforcing

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[29] It is not clear whether it is completely accurate to characterize these observations in the district court's opinion as findings of fact. Since the court had held that DDT is not a food additive, the government could not prevail unless it proved that the quantity of DDT in Vita's smoked chubs made them unfit for food or injurious to health. Clearly, the government did not sustain that burden. Under the district court's view of the law, which we have rejected, its observations about the unreliability of the government's test methods and about the sufficiency of the evidence proving excessive residues of DDT were unnecessary to its decision. On the other hand, its finding "that the test method to be used by processors of smoked chub is not sufficiently precise for a finding of fact that the chubs sampled in April 1972 contained DDT concentrations in excess of 5 ppm," 356 F.Supp. at 1221, can fairly be termed an alternative ground for granting judgment for the defendants. For if DDT in processed food was not a food additive under § 321(s), and if the government failed to prove it a known health hazard, a conclusion that the preponderance of the evidence did not sustain a conclusion that defendants' fish exceeded 5 ppm would have been unnecessary. If such a finding is in fact an alternative ground for decision, it must be sustained unless it is clearly erroneous. Rule 52(a), Fed.R.Civ.P.

a 55 mile speed limit unless a motorist's speed exceeded 65 miles per hour. Under such a policy, at a trial it would not be necessary to prove anything more than a speed in excess of 55. By comparison, the F.D.A. might as a matter of discretion withhold enforcement unless it found residues of over 5 ppm, but have not legal obligation to prove anything more than a trace to establish statutory adulteration.[30]

We do not so interpret the interim guidelines before us in this case; for both the language of the Press Release[31] and the government's treatment of it in this case[32] indicates that it was meant to operate more like a rule of general applicability than a mere prediction of how the agency

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[30] This appears to be F.D.A.'s position with respect to its 0.5 ppm guideline for mercury in swordfish, since it has contended that that guideline is without legal significance. See *Hearings on the Effects of Mercury on Man and the Environment Before the Subcomm. on Energy, Natural Resources, and the Environment of the Senate Comm. on Commerce*, 91st Cong., 2d Sess., pt. 1, at 36, cited in *Note, Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish*, 85 HARV. L. REV. 1025, 1028-1029 (1972).

[31] The 1969 Press Release stated in part:

> The interim limit of 5 ppm for DDT residues will apply to all fish marketed interstate Pesticide monitoring by FDA, however, indicates that DDT residues are below 1 ppm in 90 percent of the fish marketed in this country.
>
> Tolerances for DDT residues in other foods vary from product to product. The tolerance is .05 ppm for milk and 7 ppm for a wide variety of fruits and vegetables and in the fat of meat. FDA has taken steps to reduce a number of these where experience has shown that lower levels are practicable. App. 123.

The 0.3 ppm enforcement guideline for dieldrin has been in existence for more than 20 years. App. 62. The Record discloses no reason why its legal significance is different from that for DDT.

[32] The government engaged in a protracted evidentiary hearing for the purpose of establishing that Vita's fish contained DDT in excess of 5 ppm, without ever contending, so far as we can determine from the record, that such proceedings were unnecessary.

would choose to exercise its prosecutorial discretion.[33] Accordingly, even though the government was not obligated to adopt any interim guideline, and might have let industry accept the responsibility for initiating tolerance proceedings, it correctly assumed the burden of proving that appellant violated the specified limits.[34]

The district court considered the AOAC method of testing for chemical residues insufficiently precise for the government to sustain its burden. It is clear, however, that the enforcement guidelines must have been adopted on the assumption—shared by government and industry—that existing methods of testing DDT were sufficiently accurate to permit meaningful administration of the limits specified therein. The AOAC method was used by both the government technicians and by the expert employed by appellant.

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[33] The Press Release contains no language similar to that found in the "Merger Guidelines" released by the Department of Justice to inform the business community of its enforcement policy for Section 7 of the Clayton Act: "[T]hese guidelines are announced solely as a statement of current Department policy, subject to change at any time without prior notice . . . ." Department of Justice "Merger Guidelines," p. 1. See *United States* v. *Atlantic Richfield, Co.*, 297 F.Supp. 1061, 1073 (S.D.N.Y. 1969).

[34] *Cf. Nixon* v. *United States*, ... U.S. ...., 42 U.S.L.W. 5237 (July 23, 1974); *Vitarelli* v. *Seaton*, 359 U.S. 535, 539; *United States ex rel. Accardi* v. *Shaughnessy*, 347 U.S. 260; *United States* v. *Heffner*, 420 F.2d 809 (4th Cir. 1970). We do not suggest that there is anything to prevent the F.D.A. from changing the guideline it has enunciated, or even from enforcing the statute Congress has enacted with no guideline at all. Although there are objections to enforcement in this way, see Judge Frank's dissenting opinion in *United States* v. *449 Cases Containing Tomato Paste, supra* n. 18, the industry would clearly have a remedy in the statutory procedure for the establishment of tolerances. 21 U.S.C. § 348. We hold only that, for purposes of this litigation, the Enforcement Guideline is binding upon F.D.A., notwithstanding the informal manner of its release, as if it were a general rule published in accord with the requirements of the Administrative Procedure Act.

However imprecise that method may be, the record indicates that it is the best method that can be used. Certainly the government must be permitted to use the best testing method yet devised by analytical chemists, for the enforcement guidelines must have been predicated upon that method. Therefore, without disagreeing with the district court's observation that the AOAC method falls short of perfect certainty, we cannot accept the view that it may not be used to evaluate appellants' compliance with the guidelines. The district court's contrary determination was clearly erroneous.

Acceptance of the AOAC method as the proper standard for measuring residues of pesticide chemicals in fish leads inexorably to the conclusion that the government met its burden of proving repeated violations of the guidelines. In July and August of 1969, and again in the fall of 1969, the F.D.A. collected and analyzed smoked chubs shipped by Vita in interstate commerce and found quantities of DDT and its derivatives ranging from 5.97 ppm to 9.67 ppm. Tr. 663-665. After this case had been commenced, additional samples were anlyzed and found to contain 5.37 to 9.28 ppm [35] These samples were subsequently analyzed by an expert employed by appellant; he found that three out of the seven samples contained DDT in excess of 5 ppm and that the other ranged from 3.89 to 4.37. Finally, in October of 1972, samples were sent to Seattle for analysis with results ranging from 5.42 ppm to 6.54 ppm. Tr. 623.

Whether we accept the government's evidence at face value—and since we have held that the AOAC procedure is acceptable, and since the detailed records supporting the government's conclusion are in the record, there is persuasive reason to do so—whether we assume that the truth lies somewhere in between the views of the respective litigants' experts, or even if we take the defendants' evidence, it is

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[35] A check test, run by a second chemist, yielded a range from 6.06 ppm to 9.88 ppm. See Defendants' Ex. 15.

perfectly clear that the limit specified in the 1969 guidelines has been violated. A shipper of processed food may violate the statute even if some, or even a majority, of its food is not adulterated. The evidence is uncontradicted that the Act, as implemented by the guideline, has been violated.

Vita argues, however, that there really is no significant difference between DDT levels of 5 ppm and levels as high as 8 ppm. But that is an argument that should not be addressed to us; it may properly be asserted as a reason for setting a tolerance at 8 ppm or perhaps even higher. The F.D.A. need not have set its guideline limit at 5 ppm, but it did so, and industry has not seen fit to invoke the statutory procedures for establishing a different tolerance level. In these circumstances, the government has met its burden by proving that the guidelines have been exceeded repeatedly.

The judgment in *United States* v. *Vita Foods* is therefore reversed and remanded for the entry of appropriate relief. In view of the nature of the case and the trial judge's familiarity with the technical materials in the record, Circuit Rule 23 shall not apply.

The judgment in *United States* v. *Ewig Bros Co.* is affirmed.

UNITED STATES COURT OF APPEALS

For the Seventh Circuit
Chicago, Illinois 60604
September 26, 1974
Before

Hon. ROBERT A. SPRECHER, Circuit Judge

UNITED STATES OF AMERICA, Plaintiff-Appellant, No. 73-1454 vs. VITA FOOD PRODUCTS OF ILLINOIS INC., and LAWRENCE T. SCHWEIG, Defendants-Appellees.	Appeal from the United States District Court for the Northern District of Illinois, Eastern Division (70-C-2246)

On consideration of the motion of counsel for defendants-appellees for a stay of this Courts mandate,

IT IS ORDERED that the mandate of this Court be STAYED to and including October 18, 1974, pursuant to Rule 41(b) of the Federal Rules of Appellate Procedure.